

EXHIBIT DX1

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

EXPERT REPORT OF THEODORE R. HOLFORD, PhD

This report was prepared at the request of Corey Gordon of Blackwell Burke P.A. to provide an expert report and opinions with respect to epidemiological and biostatistical issues raised in litigation involving the 3M Bair Hugger warming system. The opinions I express herein are opinions I hold to a reasonable degree of scientific certainty and are based upon the references cited and listed herein as well as my background, training, and experience. I reserve the right to amend or add to these opinions if I learn of additional information material to my opinions.

In 1973, I was awarded a Ph.D. in Biometry at Yale University and I was chair of the Biostatistics Department at Yale School of Public Health for fifteen years. I am a fellow of the American Statistical Association and the American College of Epidemiology. In 1981, I received an Eleanor Roosevelt International Cancer Fellowship which was spent at Oxford University. In addition, I have received the Wakeman Award for Research in Neurosciences. I am currently Susan Dwight Bliss Professor of Epidemiology and Public Health (Biostatistics) at the Yale University School of Public Health. I have played a leading role in training both pre-doctoral and post-doctoral students in biostatistics and epidemiology, including assessment of the effects of environmental exposure on disease risk. I co-directed with Dr. Tongzhang Zheng on a Fogarty training program entitled "Cancer Epidemiology and Biostatistics Training in China" which included the conduct of workshops on methods for cancer epidemiology research in China, as well as the mentoring of trainees on their individual research projects.

My research involves the development and application of statistical methods in public health and medicine. This work led to the publication of a text book entitled *Multivariate Methods in Epidemiology*.¹ I am recognized for developing an approach for analyzing temporal trends in disease rates using the age-period-cohort modeling framework that is used extensively in the analysis of cancer incidence and mortality trends. Currently, I am extending and applying these concepts in a population model for lung cancer and other diseases related to cigarette smoking that can be used for evaluating cancer intervention strategies as part of the Cancer Intervention and Surveillance Modeling Network (CISNET). This work has appeared in a variety of scientific journals including the *Journal of the American Medical Association* and *Journal of the National Cancer Institute*. My CV is attached at exhibit A.

This report is a review of the observational study of risk for deep infection following use of Bair Hugger warming device during knee and hip replacement surgery compared to Hot Dog conducted by McGovern et al.² This is the only study to my knowledge that has directly compared risk during periods in which each of these devices was used. As part of the depositions of Mr. Mark Albrecht,³ Dr. Michael Reed,⁴ and Dr. Paul McGovern⁵ data were provided on the experience at Wansbeck General Hospital, which is part of the Northumbria Healthcare NHS Foundation Trust, that formed the basis for the McGovern study, as well as some time before and after the study (see Albrecht deposition exhibit 10; McGovern deposition exhibit 16) This study was the primary source of a review by Dr. Jonathan Samet⁶ which considered this work in drawing a scientific inference on whether there is evidence for inferring a

causal association between risk of deep infection and use of the Bair Hugger warming device during surgery.

In order to consider the question of a causal association, results from the McGovern study were first audited in an attempt to reproduce the results that appear in the McGovern paper.² This report then continues with a discussion of the impact that any changes in results might have on inferring an association that can be justified as being causal, as suggested in a report by Samet.⁶

Conclusions from the McGovern study

As part of a bubble study of air flow in an operating room using the Bair Hugger compared to the Hot Dog, McGovern et al. conducted an observational study of infection rates for a retrospectively chosen period when the Bair Hugger device was used for surgeries conducted at Wansbeck General Hospital (7/1/2008 to 3/1/2010). This was compared to a period in which the hospital had switched to Hot Dog use (6/1/2010 to 1/1/2011). Data that included these periods from Wansbeck General Hospital were produced by Dr. Scott Augustine in response to a subpoena (Albrecht deposition exhibit 10) and were discussed as part of depositions from Mr. Mark Albrecht,³ Dr. Mike Reed⁴, and Dr. Paul McGovern,⁵ Dr. McGovern also produced a spreadsheet with infection data (McGovern deposition Exhibit 16). These data and the clarifying testimony from these three study authors were used in an attempt to validate results reported by McGovern et al.² and reviewed in the report by Samet.⁶

Infection proportions by selected warmer use

Analysis of the data file (Albrecht Ex. 10) using SAS 9.4[®] shows $4/372=1.08\%$ infections during Hot Dog use and $31/1065=2.91\%$ during Bair Hugger use. Chi-square works well for comparing proportions when the sample size is large, but Fisher's exact test gives an accurate P-value whether the sample size is large or small.⁷ For these data, the sample size is small, so Fisher's exact test is most appropriate, giving two-sided $P=.0507$ which is not statistically significant in that it is greater than .05. McGovern et al.² use the chi-square test, which for this tabulation is $X^2=3.9089$, $df=1$, $P=.0480$ which is just below the conventional limits to be considered statistically significant (0.05). The difference between these two significance tests is not great in magnitude, but the conclusions change from not significant to being significant, the former being the more accurate test.

The odds ratio for this comparison is 2.76 and the 95% exact confidence limit is 0.97-10.82, which is wide and inclusive of the null value of 1. The wide confidence interval, in this case the range is ten-fold, demonstrates that the estimated association is not precise and it actually includes the null value of 1. This does not by itself necessarily suggest bias, but instead the lack of precision that has resulted from a study of this size. Reliance on a single observational study, especially when the confidence interval is so wide and includes the null value of 1, to reach a conclusion that a causal relationship has been demonstrated is not justified scientifically.

Results from the paper by McGovern et al.² are incorrectly given as $3/371=0.81\%$ for Hot Dog and $32/1066=3.00\%$ for Bair Hugger. Using this tabulation, Fisher's exact test gives $P=.0176$, although chi-square is used in the paper, $X^2=5.5529$, $df=1$, $P=.0185$. The odds ratio is larger, 3.79 with an exact confidence interval of 1.15 to 12.45, which is also wide but it does not include the null value. Wide confidence limits reflect the lack of precision for the estimate of the odds ratio, and it is a result of the relatively small sample size in the McGovern study. The results reported by McGovern are incorrect,

however, because they arise from an incorrect tabulation, an error is recognized in the depositions by Albrecht,³ Reed⁴ and McGovern.⁵

The testimony of Dr. Reed and Mr. Albrecht demonstrates that the infection rates that appear in the published McGovern analysis were in error.^{3,4} Dr. Reed testified that there was one more infection in each group, and Mr. Albrecht testified that the published data differed “slightly” from the newer dataset he had been provided. (Mr. Albrecht had recalculated an odds ratio of 2.98 based on the updated data). Further insight into the errors in data tabulation can be gleaned from the spreadsheet produced by Dr. McGovern (Exhibit 16), which lists the dates and types of procedures that resulted in infections. Of significance, the data on the McGovern spreadsheet include infection data from several months prior to the start of the Bair Hugger-only period, as is the case with Albrecht Exhibit 10. All details of the infections in these earlier data on the McGovern spreadsheet correspond exactly with the data on Albrecht Exhibit 10, giving verification that the data in Albrecht Exhibit 10 were the same data upon which the published study was based. Albrecht Exhibit 10, however, provides data for a few additional months past December 2010, the end of the Hot Dog only period in the published McGovern study. The McGovern spreadsheet stops at the end of December 2010, providing further support that the data on this spreadsheet were the data used in preparing the published paper. In examining the McGovern spreadsheet, it is noted that dates at the beginning of the spreadsheet are expressed in the format customary in the U.K. (day/month/year) while dates at the end of the spread are noted in the customary U.S. manner (month/day/year). The McGovern spreadsheet, unlike the full dataset, has a column indicating whether FAW (Bair Hugger) or CFW (Hot Dog) was used. For one entry on the McGovern spreadsheet, Sept. 15, 2010, the warming device is coded as FAW, meaning Bair Hugger. However, the hospital had fully transitioned to Hot Dog by the end of May, 2010, and Dr. McGovern could not explain why there would have been a surgery conducted three and ½ months after the transition using a Bair Hugger. The only plausible explanation consistent with the published information about when each warming unit was being used, as well as Dr. Reed’s testimony about the errors in the published data and Mr. Albrecht’s acknowledgement that there were “slight” data errors (that resulted in a lower odds ratio), is that, in coding the type of warming device used on the McGovern spreadsheet, someone erroneously categorized the Sept. 15, 2010 surgery as having used a Bair Hugger instead of a Hot Dog. If the Sept. 15, 2010 procedure is counted as a Hot Dog procedure rather than a Bair Hugger procedure, the McGovern spreadsheet then perfectly matches the data on Albrecht Exhibit 10 and explains the errors noted by Dr. Reed and Mr. Albrecht.

Hence, one infection that McGovern tabulated among the Bair Hugger infections should have been counted within the Hot Dog period. The tabulation based on this correct information is shown in the first paragraph of this section.¹

Infection rate comparison among hospitals

Figure 1 provides a summary of the distribution of infection rates following hip or knee surgery for reporting institutions in the National Health Service that used the Bair Hugger from 2010 to 2015 (based on data from NHS trust tables reporting the experience of infections from hip and knee surgery at trust hospitals.⁸ Identification of trusts using Bair Hugger was provided by 3M). No infections were reported

¹ Even if one assumes that Dr. Reed’s recollection in his deposition was correct (that there was one additional infection in each group), the odds ratio is nevertheless markedly different than reported in the published paper: $33/1066 = 3.1\%$ for the Bair Hugger period, $4/37 = 1.08\%$ for the Hot Dog period; $OR = 2.86$, $CI\ 1.03-8.33$, $P = .0356$

in $36/128=28\%$ of the hospitals. As we have noted above, Wansbeck General Hospital had an infection rate of $31/1065=2.91\%$ during the period used to characterize the experience under Bair Hugger, shown by a red "X" in Figure 1, compared to $444/73,947=0.60\%$ among NHS Trusts using the Bair Hugger from 2010 to 2015. Thus, one would expect to see just 6.39 infections at Wansbeck General Hospital during the period selected by the authors for the Bair Hugger only cohort, but 31 were observed. The significance of this difference yields $X^2=95.25$, $df=1$, $P<.00001$. Clearly, the rate of infection at Wansbeck General Hospital during this period was far higher than the normal experience among other hospitals in the National Health Service, indicating that the infection rate at Wansbeck General Hospital was not in control during this period. Reed describes aggressive measures undertaken during this period by the Northumbria Healthcare Foundation Trust, which includes Wansbeck General Hospital, to control orthopedic surgery infection.⁹ Gillson and Lowdon,¹⁰ also discuss the fact that infection rates were indeed out of control at Northumbria Healthcare NHS Trust, which includes Wansbeck General Hospital, during this period and they describe multiple efforts that were introduced in order to bring the infection rate in line with what would normally be expected. The heating device was not the only factor being changed during this time.

The impact of other infection control practices on the infection rate during this time period is addressed by other experts retained by counsel for 3M and is beyond the scope of my opinion. I note, however, that the various infection control practices implemented in an effort to rein in a serious infection problem that had gotten out of control should have been considered, individually and collectively, in assessing the impact of the method of patient warming on infections rates, and the failure to do so injects bias into any univariate comparison of two different warming methods used during this period of time, bias that cannot be corrected for through statistical methods now.

Time trend in infection rates at Wansbeck General Hospital

Time trend of the infection rates were estimated using a 60-day window around each day from 9/1/2007 to 1/1/2011, and they are displayed by the solid blue line in Figure 2. The rates are approximately 1% after 6/1/2010 and somewhat lower before the start of the McGovern study in 7/1/2008, a time when Bair Hugger was being used but before the start of the period that McGovern et al. selected for the period of Bair Hugger-only use. Figure 7 as published in McGovern et al.² shows a constant infection rate which is the assumption on which their significance test is based. (In an earlier draft of this manuscript, Figure 7 shows considerable variability in the infection rate during the Bair Hugger period [McGovern Deposition Exhibit 7A, p.2218]. This was not shown in the published version which instead suggests that the rate was constant during this period.) Our estimate that uses the correct tabulation of the data on the overall rates during the study periods is shown by the green line in our Figure 2. The estimated trend is clearly very different from the trend which forms the basis of the significance test shown for the Bair Hugger vs. Hot Dog comparison.

In order to assess whether the variability in trend is just a chance occurrence, the Bair Hugger period used by McGovern et al.² was divided into quarters beginning 7/1/2008, which is shown by the broken blue line in Figure 2. The last quarter ends on 3/1/2010, the last day for this treatment period. A chi-square test for equality of infection rates by quarter during the Bair Hugger period yields $X^2=15.50$, $df=6$, $P=.0167$. Thus, there is strong evidence that the rates were highly variable during this time, and Figure 2 suggests that there were actually two separate outbreaks of infection, the second near the end of the Bair Hugger-only period being especially severe. The two months at the start of 2010 had $9/107=8.41\%$ infections following surgery, 14 times the rate seen on average by National Health Service hospitals.

Variability like this strongly indicates a period in which infections were not well controlled, which once again supports the rationale for the aggressive interventions which are described by Reed⁹ and by Gillson and Lowdon.¹⁰

Selection of start date for study

Reasons that McGovern et al. started the Bair Hugger period on 7/1/2008 are not clear. Bair Hugger was standard practice at Wansbeck General Hospital, and one could well justify starting even earlier in order to increase the sample size for the study and thus improve the power. If one were to start follow-up on 10/1/2007, for which data were available and included in the complete dataset (McGovern Exhibit 16), the difference in infection rates is not close to being significant, $P=.2179$ using Fisher's exact test, with an odds ratio of 2.12 (95% confidence interval of 0.75-6.00). If the infection rates were indeed constant, one would expect the P-value to become even smaller because of the increase in the sample size due to the increase in the number of operations during the extended duration. However, Figure 2 shows that the rate is actually much lower during this time period when the rates were under control and close to the experience seen at other hospitals in the National Health Service.

McGovern et al.¹⁰ employed the chi-square test as the test of significance. In Figure 3 we show chi-square using alternative months for starting the Bair Hugger period, beginning 10/1/2007. We see that the chi-square statistic increases with time, finally crossing the value of 3.84, the critical value for statistical significance at $P=.05$, on 7/1/2008, the date used by McGovern et al.² to start the study period, showing statistical significance at the 5% level using the chi-square test. The starting point for the Bair Hugger-only period used in the McGovern et al. analysis coincided with a time when the infection rate was beginning to increase as infection control was being lost at Wansbeck General Hospital. Results reported by McGovern are a function of the lack of infection control during this period. Had the Bair Hugger-only study period been chosen to start even one month earlier, the results would not have not reached statistical significance.

Comparison of the effect of thromboprophylaxis regimen on study results

Jensen et al.¹¹ conducted a study of the use of rivaroxaban, which was introduced into the Wansbeck General Hospital surgery for knee and hip replacement from 8/1/2009 to 2/28/2010. These were compared to the rates when tinzaparin was used from 2/1/2009 to 7/31/2009. The entire Jensen study period took place within the Bair Hugger period used by McGovern et al.² and this was also the period that Wansbeck General Hospital was experiencing considerable variability and high rates of infection. Two important differences between the McGovern et al. and the Jensen et al. studies are: (a) McGovern limited recruitment to non-trauma cases while Jensen did not, which yielded more operations in both arms of the Jensen study; and, (b) Jensen reported infections diagnosed within 30 days of surgery while McGovern used a 60 day limit.

Jensen et al.¹¹ report $5/489=1.02\%$ infections for the tinzaparin cases and $14/559=2.50\%$ for rivaroxaban, Fisher's exact $P=.1026$, $OR=2.49$, $95\% CI=0.89-6.95$, which is not statistically significant. However, if one adopts the same inclusion and outcome criteria used by McGovern² then the results are $3/307=0.98\%$ for tinzaparin and $18/400=4.5\%$ for rivaroxaban, Fisher's exact $P=.0064$, $OR=4.77$, $95\% CI=1.37-25.49$. The latter results are more relevant for the question of whether use of this medication was an important confounder for the McGovern study because it is specifically applied to the same type of patient with a comparable definition of the outcome. Hence, these data do strongly point to rivaroxaban use to be an important confounding variable because it is associated both with the

outcome, deep infection, and type of warmer used, i.e., rivaroxaban was *only* used during the Bair Hugger period.

A potential confounding factor, like rivaroxaban or tinzaparin use, should be controlled in the analysis in order to obtain valid estimates for the comparison of Bair Hugger and Hot Dog. Controlling for type of thromboprophylactic in this case can be done by using only the Bair Hugger period when tinzaparin is used, the thromboprophylactic shared by patients in both groups (7/1/08 to 7/31/09). In this case, the results are $4/372=1.08\%$ for Hot Dog and $22/958=2.30\%$ for Bair Hugger, with Fisher's exact $P=.1874$, $OR=2.16$, $95\% CI=0.73-8.69$. These results do not support a conclusion that there is a strong association of infection risk with Bair Hugger use as they are well within what might have expected by chance alone.

In my analysis here, only a single potential confounding variable has been controlled. Clearly, other changes described by Dr. Reed as well as Gillson and Lowdon¹⁰ could also have an effect. If anything, it is likely that they would have attenuated the estimated association still further.

Comparison of the effect of antibiotic regimen on study results

On March 1, 2009 the antibiotic regimen used at Wansbeck General Hospital was changed from Gentamicin 4.5 mg/kg to Gentamicin 3 mg/kg and Teicoplanin 400 mg. During the period when Bair Hugger was used with Gentamicin 4.5 mg/kg, $13/676=1.92\%$ was the rate of infection and when Gentamicin 3 mg/kg and Teicoplanin was used, the rate was $21/670=3.13\%$. The difference is not statistically significant, $P=0.1683$.

In order to control for both thromboprophylactic and antibiotic, one must use the Bair Hugger period that shares the same antibiotic and thromboprophylaxis regimen used during the Hot Dog period, i.e., March 1, 2009 to July 31, 2009, which had an infection rate of $3/270 = 1.11\%$ compared to $4/372 = 1.08\%$ during the Hot Dog period, $P=1.000$. As McGovern et al. co-author and statistician Mark Albrecht³ conceded in his deposition, once the antibiotics and thromboprophylaxis regimen are controlled for, there is no difference in infection rates between Bair Hugger and Hot Dog. In this case, all of the difference in risk is accounted for by these two confounding variables.

Conclusions regarding the McGovern et al. findings

My analysis of the data used in the McGovern et al.² study indicates that they do not support a conclusion that risk of deep infection is greater when Bair Hugger is used compared to Hot Dog. Reasons why the McGovern et al. conclusions are not valid are:

1. The tabulation provided by McGovern is not accurate because one of the cases in the Hot Dog group was incorrectly switched to the Bair Hugger group. In addition, numbers are small, so that the Fisher's exact test would be preferred over the chi-square test which uses an approximation. Correcting these errors yields a P-value greater than .05, which is close but not statistically significant.
2. The period attributed to Bair Hugger use shows that the infection rate at Wansbeck General Hospital was out of control, as can be seen by:
 - a. The rate of deep infection was far higher than other hospitals in the National Health Service, $P<.00001$;
 - b. The infection rate varied considerably during the Bair Hugger period, the experience that one would expect when conditions were not being well controlled;

- c. Results are very sensitive to the start date, an effect that is caused by the infection control difficulty being experienced by Wansbeck General Hospital during the Bair Hugger period; and,
 - d. Many different control measures were being implemented at Wansbeck General Hospital during the time these surgeries were being performed. There is very strong evidence that the thromboprophylactic being used was in and of itself strongly associated with the infection rate in these patients and it was only used during the Bair Hugger period.
3. Controlling for potential confounding variables is always a serious concern in observational studies, especially when two time periods are being compared. Inevitably, more than one factor will change with time. In these data, there is strong evidence of an association with infection risk from at least one such variable: thromboprophylaxis. Controlling for just this one confounding variable largely explains the difference between the infection rates for Bair Hugger and Hot Dog use. If one also controls for the antibiotic regimen, the infection rates are virtually identical.

Causation findings.

Assessment of factors thought to be possible risk factors for disease can be a challenge to unambiguously identify. This can best be accomplished by conducting a well-designed experiment in which only the factor of interest is changed while all other potential risk factors have been held constant. The identification of cigarette smoking as a major, if not **the** major risk factor for lung cancer has been one of the greatest successes in public health during the twentieth century, and as Professor Samet correctly points out, this was done through careful analysis of observational studies that did not include designed experiments such as randomized controlled clinical trials. However, there were multiple studies directly addressing health effects that yielded consistent results so that taken together, they provided overwhelming evidence that there was a harmful effect on human health and that effect was substantial. The robust and consistent data from multiple studies provided a way forward for launching policies that would reduce what had become a catastrophe.

Professor Samet likens our knowledge of the underlying science on risk of deep infection affected by the Bair Hugger and Hot Dog surgical warming devices to cigarette smoking and lung cancer. The beginning of a broad consensus in the public health community around the adverse effect of cigarette smoking and health risk is well summarized in the first Surgeon General's Report on smoking and health which appeared in 1964.¹² On lung cancer alone, this report included results from 29 retrospective studies, all but one of which found excess risk among cigarette smokers (p.27), and 7 prospective studies (involving more than 1 million people in three different countries) The estimated associations were far stronger than what is found for the Bair Hugger and Hot Dog comparison. In Table 4 on p.161, for example, relative risks for smokers of more than 1 pack/day or heavy smokers had relative risks that range from 10.8 to 34.1.¹² The evidence regarding the harmful effect of cigarette smoking has grown enormously since 1964.¹³ For the Bair Hugger v Hot Dog comparison we have but one study with a point estimate of 2.76 that is not statistically significant and largely explained by confounding variables. There is no similarity between the current state of the science related to the Bair Hugger and the evidence on cigarettes even 50 years ago. Reliance on a single, flawed study to infer a causal relationship is not consistent with valid scientific methodology in general, and it does not compare with the methodology that resulted in the conclusion that cigarette smoking causes lung cancer.

However, the logic for causal inference drawn from observational epidemiologic research is relevant for trying to understand the evidence on warming devices. To draw scientific conclusions on the state of existing evidence, it is useful to consider criteria for determining causality like those suggested by Samet:⁶

1. Temporality
2. Strength of association
3. Consistency
4. Coherence

In the discussion below, these criteria are reviewed while taking into account the new analyses of the data from which the McGovern study were drawn.²

Temporality

Samet points out that temporality must hold if a factor of interest is a cause for a particular disease. This is obviously satisfied for exposure to Bair Hugger and Hot Dog. It is also satisfied for tinzaparin and rivaroxaban as a potential confounding factor under consideration, as well as other infection control practices implemented prior to the switch to Hot Dog.

Strength of association

The point estimate for the association between Bair Hugger and Hot Dog referred to by Samet is 3.8, which is reported by McGovern et al.² This estimate of effect is not actually supported by a corrected analysis of the data because:

1. One subject said to be in the Bair Hugger group was actually in the Hot Dog group. Correcting this tabulation changes the test for significance from statistically significant to not statistically significant. The correct estimate for the odds ratio is 2.76 and the 95% CI= 0.97-10.82. The confidence interval is wide and actually includes the null value of 1. Hence, it is not a strong indication of an adverse health effect.
2. The period used to represent the experience for the Bair Hugger exposure was one in which infections were out of control at this hospital. This is indicated by:
 - a. Significantly higher rate of infection compared to other hospitals in the National Health Service that also used the Bair Hugger device.
 - b. Strong evidence of instability and temporal variability in the incidence rate during the period used.
 - c. Sensitivity to the start date used, which coincided with what can be seen to be the start of the time when control of infections was being lost at Wansbeck General Hospital.
3. Not even a single potential confounding variable was included in any of the analyses. Samet argues that this would be unlikely to affect the conclusions because of the magnitude of the estimated association. However, he shows no data to support this view. This conclusion, in fact, is not scientifically valid because:
 - a. The estimate of the association is actually considerably smaller than what is cited, 2.8 and not 3.8 when one uses the correctly tabulated data.
 - b. Use of rivaroxaban was dismissed as a potential confounding variable based on the lack of statistical significance reported by Jensen et al.¹¹ However, Breslow and Day¹⁴ show that statistical significance is not essential for a factor to confound an estimated

association and a factor can be a confounder even if the association is not statistically significant. In order for a factor to be a confounder it must be associated both with treatment exposure and with the outcome. Rivaroxaban was only used during the Bair Hugger period, so it is clearly associated with treatment. While Jensen et al.¹¹ did not find a significant effect for rivaroxaban, the study used different criteria than that used by McGovern et al. A reanalysis using data that are consistent with the criteria used by McGovern et al.² do show quite strong and statistically significant evidence that it is associated with risk of deep infection in this group of non-trauma patients. More importantly, after controlling for rivaroxaban use the Bair Hugger/Hot Dog result is not close to statistical significance ($P=.1874$), establishing that thromboprophylaxis is in fact a confounding factor.

- c. The period of time being used as representative of the broad experience seen for Bair Hugger use clearly shows a much higher rate of infection than normal experience. In addition, there is strong evidence of fluctuation during this period, which is what is commonly seen when a surgical facility is having difficulty controlling infection.
- d. Because Wansbeck General Hospital was experiencing a problem controlling infection, aggressive action was taking place in an attempt to bring it into control, as described by Reed,⁹ as well as Gillson and Lowdon.¹⁰ These activities were intended to drive down the infection rates, and the data indicate that this was largely accomplished by the time that Hot Dog use began at Wansbeck General Hospital.

Consistency

The only epidemiological study considered by Samet is McGovern et al.² In fact, there is no consistent evidence of a harmful effect of Bair Hugger use because no other study is currently available. This is in sharp contrast to the evidence linking cigarette smoking and cancer.

Instead, Samet describes some consistency among studies in which the outcome is the distribution of particles in experimental conditions in studies conducted by investigators employed and/or supported by a competitor of Bair Hugger. Particles are at most an intermediate outcome that has not been shown to directly relate to the outcome of interest, deep infection. Repeated efforts by this group of investigators failed to show that Bair Hugger increased spread of the number of bacteria that cause deep infection, as described by Albrecht,³ McGovern⁵ and Legg.¹⁵ The unpublished results of these unsuccessful efforts to link Bair Hugger use with an increase in bacterial burden are also alluded to in published papers by this group.^{16,17} The field of microbiology is beyond my area of expertise, so I leave it to others to discuss this evidence further. However, no direct scientific evidence of a causal link supporting the hypothesis that Bair Hugger use is associated with an increased risk of deep infection is provided, other than McGovern et al.²; thus, there is no consistency.

Coherence

The concept of coherence across the various lines of evidence currently available on deep infection risk for Bair Hugger compared to Hot Dog does not hold, as proposed by Samet. The breakdown in the coherence arises because:

1. There is only one very flawed epidemiological study reporting an association. The work above documents not only the problems in the way that the McGovern et al. study was conducted, but also in the analysis that (a) used an incorrect tabulation of data; (b) a period of time when the

infection rate for the hospital was out of control and not representative of the broad experience with using the Bair Hugger; and, (c) failure to control for confounding variables that can account for the reported results.

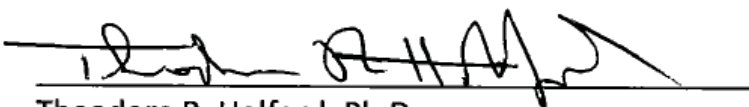
2. The studies reported to be consistent dealt with particles in general, not bacteria shown to cause deep infection. Studies that examined the impact of Bair Hugger use show an effect on particle distribution,^{18,19} but not viable particles, i.e., bacteria, as described by Albrecht.³ Hence, the relevance of these particle studies to the scientific question of interest is lacking.

Conclusion

The current state of knowledge regarding a causal association of deep infection risk with use of Bair Hugger compared to Hot Dog is not supported by the underlying science. A single, limited, and flawed observational study cannot provide the rigorous scientific evidence needed to show a causal effect. A single observational experience inevitably has many potential factor changes, some of which are measured and some are not. Arbitrarily picking two periods of time to compare are particularly problematic, because one or more factors are being changed and balance between the groups has not occurred.

This analysis has shown that the data used by McGovern et al.² do not show an association with risk when the tabulated results have been corrected and a confounding factor has been appropriately controlled. In addition, the comparison period used to represent the experience under Bair Hugger is one in which the infections at Wansbeck General Hospital were not being well controlled and thus not a good representation of the experience in the National Health Service.

A copy of my CV, including list of publications, is attached hereto. Materials I reviewed and considered in preparing this report are referenced herein and included in the list of references. I am being compensated at the rate of \$500.00 per hour for my work on this matter. I have not testified as an expert in any other matter in the previous four years.



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Date

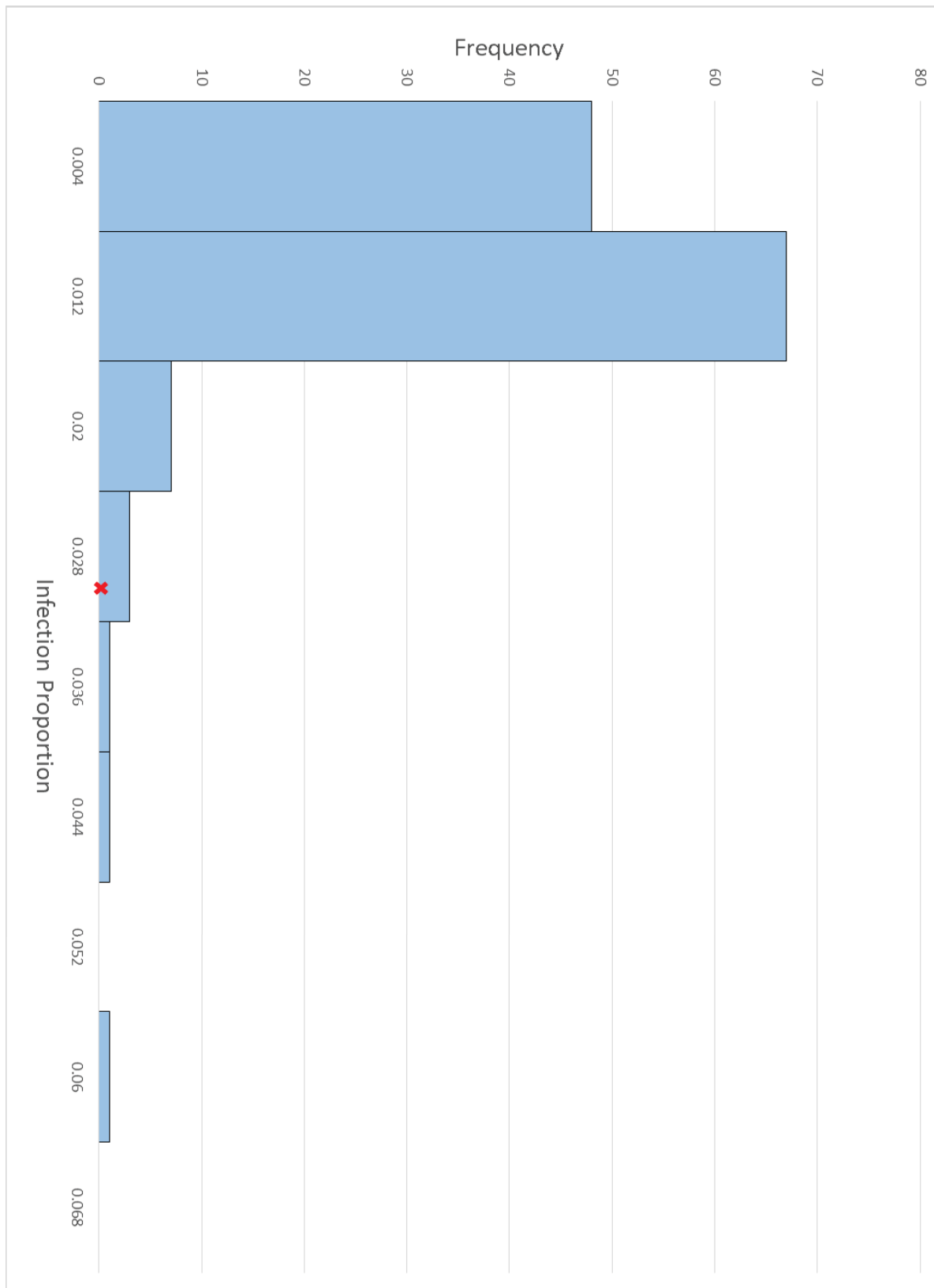


Figure 1. Distribution of hospital infection rates for National Health Service hospitals, 2010-2015.

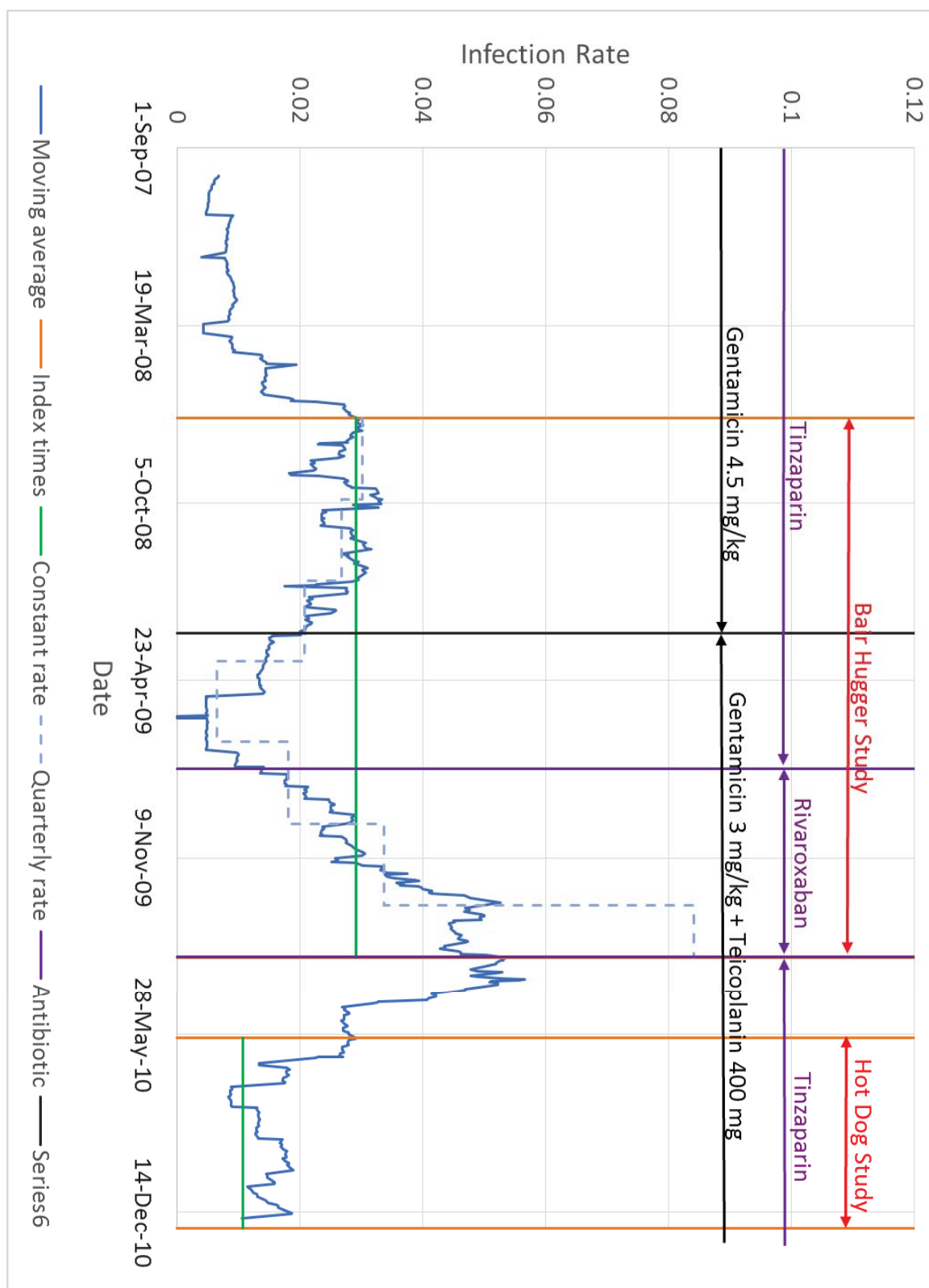


Figure 2. Time trend for infection rates and events: 60-day moving average (solid blue), quartile rates during Bair Hugger use (broken blue), constant rate (solid green), McGovern Study periods (solid orange), thromboprophylaxis used (purple), antibiotic used (black).

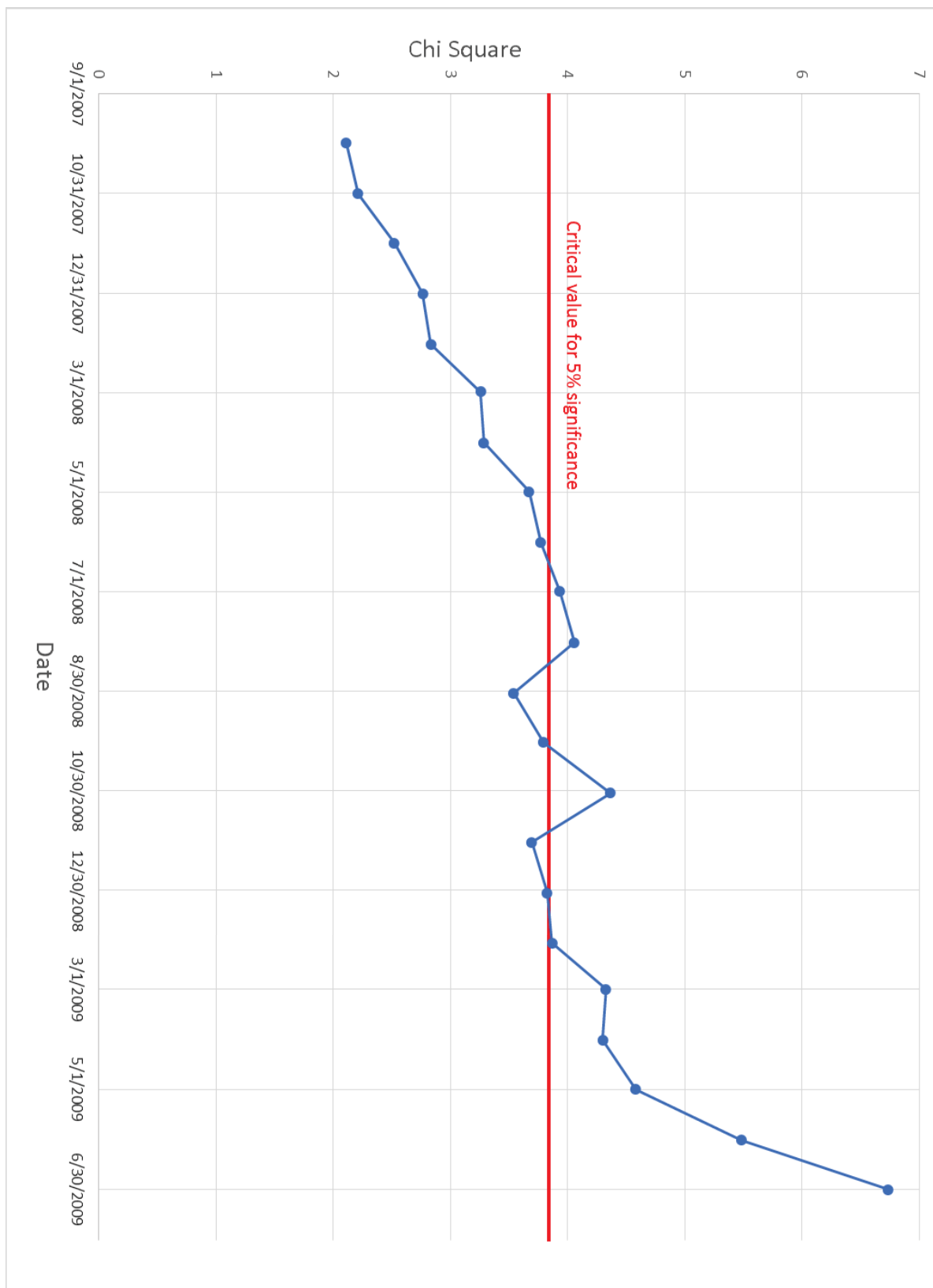


Figure 3. Trend in chi-square with date of start of study.

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3. Videotaped deposition of Mark Albrecht. United States District Court, District of Minnesota; 2016.
4. Videotaped Deposition of Michael R. Reed. United States District Court: District of Minnesota; 2016.
5. Deposition of Paul McGovern. United States District Court, district of Minnesota; 2017.
6. Samet JM. *Expert Report of Jonathan M. Samet, M.D., M.S.* United States District Court: District of Minnesota; 2016.
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10. Gillson J, Lowdon G. Implementing effective SSI surveillance. *The Clinical Services Journal*. 2014;71-74.
11. Jensen CD, Steval A, Partington PF, Reed CE, Muller SD. Return to theatre following total hip and knee replacement, before and after the introduction of rivaroxaban. *The Journal of Bone and Joint Surgery (Br)*. 2011;93-B(1):91-95.
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13. US Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.
14. Breslow NE, Day NE. *Statistical Methods in Cancer Research*. Vol 1 - The analysis of case-control studies. Lyon: International Agency for Research on Cancer; 1980.
15. Videotaped deposition of Andrew John Legg. United States District Court: District of Minnesota; 2016.
16. Legg AJ, Cannon T, Hamer AJ. Do forced air patient-warming devices disrupt unidirectional downward airflow? *The Journal of Bone and Joint Surgery*. 2012;94-B:254-256.
17. Legg AJ, Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. *The Bone and Joint Journal*. 2013;95-B:407-410.
18. Albrecht M, Gauthier R, Leaper D. Forced-air warming: a source of airborne contamination in the operating room? *Orthop. Rev. (Pavia)*. 2009;1:e28:85-89.
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CURRICULUM VITAE

Name: Theodore R. Holford

Appointment: Susan Dwight Bliss Professor of Public Health (Biostatistics)

School Assignment: School of Medicine and Graduate School

Education:

1965-1969	B.A., Andrews University - Mathematics and Chemistry with honors
1969-1973	Ph.D., Yale University - Biometry Thesis: Stochastic Models in Schistosomiasis and Their Application to Epidemiologic Data

Career:

9/72 - 12/73	Research Staff Biometrician, Yale University (Research Associate for the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents)
1/74 - 6/79	Assistant Professor of Public Health (Biometry), Yale University
7/81 - 7/82	Sabbatical leave at the Department of Biomathematics, University of Oxford
7/84 - 6/85	Acting Head, Division of Biostatistics, Department of Epidemiology and Public Health, Yale University
7/79 - 6/89	Associate Professor of Public Health (Biostatistics), Yale University (tenure on 7/83)
7/89 - present	Professor of Public Health (Biostatistics), Yale University School of Medicine
7/90-6/97, 7/03-6/11	Head, Division of Biostatistics, Department of Epidemiology and Public Health, Yale University School of Medicine
7/93 –present	Professor of Statistics, Yale University
7/97 – 6/02	Director of Graduate Studies, Department of Epidemiology and Public Health, Yale University School of Medicine

7/99 – 6/02	Associate Director, Investigative Medicine Program, Yale University School of Medicine
1/01-6-01	Triennial Leave at Division of Cancer Control and Population Sciences, Surveillance Research Program, National Cancer Institute, Rockville, MD.
7/01 - 12/01	Acting Dean for Public Health and Acting Chair, Department of Epidemiology and Public Health, Yale University School of Medicine
11/02 - present	Susan Dwight Bliss Professor of Public Health (Biostatistics), Department of Epidemiology and Public Health

Professional Honors or Recognition:

Honors from regional and national organizations:

7/81-7/82	Recipient of an Eleanor Roosevelt International Cancer Fellowship from the UICC (International Union Against Cancer)
10/90	Recipient of the Wakeman Award for Research in the Neurosciences
9/97	Fellow of the American College of Epidemiology
8/05	Fellow of the American Statistical Association
2/14	Elected member of Connecticut Academy of Science and Engineering

Other awards or honors

11/02	Appointed Susan Dwight Bliss Professor of Public Health (Biostatistics)
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Lectures, Courses

May, 1973. Life tables with concomitant information. 1973 Spring Regional Meetings of the Biometric Society, Ithaca College, Ithaca, New York.

May 10-13, 1976. Workshop on mathematical models in schistosomiasis. Bellagio, Italy.

April, 1977. Multivariate methods for matched case-control studies. 1977 Spring Regional Meeting of the Biometric Society (ENAR), University of North Carolina, Chapel Hill, North Carolina.

August, 1977. Log-linear representation for matched case-control studies. Annual Meeting, American Statistical Association, Chicago, Illinois.

- August, 1978. Log-linear models with adjustment for follow-up time. Annual Meeting, American Statistical Association, San Diego, California.
- August, 1979. Invited paper. The application of log-linear models to the analysis of case-control studies. Annual Meeting, American Statistical Association, Washington, D.C.
- June, 1980. Invited paper. Multivariate analysis of case-control studies using log-linear models. Annual Meeting of the Society for Epidemiologic Research, Minneapolis, Minnesota.
- August, 1980. Survival from colorectal cancer in Connecticut, 1960-1976. Annual Meeting, American Statistical Association, Houston, Texas.
- March, 1981. Invited paper. The analysis of age-period-cohort trends in vital rates. Spring Regional Meeting of the Biometric Society (ENAR), Richmond, Virginia.
- May, 1981. Invited paper. Methods of adjusting for covariates in survival analysis. Annual Meeting of the Society for Clinical Trials, San Francisco, California.
- July, 1981. Invited participant in a Conference on the Effects of Low Dose Ionizing Radiation, Coolfont, West Virginia.
- February, 1982. Invited paper. Analysing censored survival data in large datasets. Meeting of the Biometric Society, London.
- March, 1982. Invited paper. The estimation of age, period and cohort effects for vital rates. Meeting on Medizinische Statistik, Mathematisches Forschungsinstitut Oberwolfach, Federal Republic of Germany.
- June, 1984. Invited participant in a Student Workshop on Epidemiologic Methods. Society for Epidemiologic Research. Houston, Texas.
- August, 1984. Invited paper. Problems in presenting time trends in cancer incidence rates. Annual Meeting, American Statistical Association, Philadelphia, Pennsylvania.
- June, 1986. Invited paper. Regression models for epidemiologic analysis. Society for Epidemiologic Research. Pittsburgh, Pennsylvania.
- August, 1986. Invited paper. Projecting trends in cancer incidence. Annual Meeting, American Statistical Association. Chicago, Illinois.
- Summer, 1987. Graduate Summer Session in Epidemiology at the University of Minnesota.
- Summer, 1988. Graduate Summer Session in Epidemiology at the University of Michigan.

- March, 1989. Estimating the distribution of trends in Helper T lymphocytes following HIV infection. Spring Meeting, The Biometric Society, Eastern North American Region, Lexington, Kentucky.
- Summer, 1989. Graduate Summer Session in Epidemiology at the University of Michigan.
- August, 1990. An empirical evaluation of the properties of the standardized proportional mortality ratio. International Epidemiological Association, Los Angeles, California.
- October, 1991. Invited paper. Time trends: Are they real? And what do they mean? Workshop on the Time Trends in Non-Hodgkin's Lymphoma. National Cancer Institute, Bethesda, Maryland.
- December, 1993. Invited paper. Update on the Third National Acute Spinal Cord Injury Study (NASCIS III). Neurotrauma Society, Washington
- August, 1994. A population model for the effect of smoking on lung cancer incidence. International Biometric Conference, Hamilton, Ontario.
- September, 1998. Modeling the effect of cigarette smoking on population incidence rates. Symposium on Epidemic Modelling, Australian National University, Canberra, Australia.
- June, 2000. Analysis of disease trends in time and space. Spotlight Session, Society for Epidemiologic Research. Seattle, Washington.
- June, 2000. Joint Effects of Nine PCB Congeners on Breast Cancer Risk. Poster Session, Society for Epidemiologic Research. Seattle, Washington.
- May, 2001. Spatial modeling of age, period and cohort effects. Invited paper. EPA Conference on Environmental Statistics and Information. Philadelphia, Pennsylvania.
- June, 2001. Spatial Modeling of Age, Period and Cohort Effects. Invited paper. Washington Statistical Society, Washington, D.C.
- December, 2001. Spatial Modeling of Age, Period and Cohort Effects. Invited paper. Connecticut Chapter of the American Statistical Association. Wallingford, Connecticut.
- March, 2002. Approaches to fitting age-period-cohort models with unequal intervals. Spring Meeting, The Biometric Society, Eastern North American Region, Arlington, Virginia.
- June, 2004. Age, Period, Cohort Analysis of the Variation in Temporal Trends for Lung Cancer Incidence among Connecticut Towns, 1973-2002. Poster presented at Society for Epidemiologic Research Meeting, Salt Lake City, Utah.
- August, 2004. Spatial Summaries of Small Area Temporal Effects from an Age-Period-Cohort Model. Presentation at the Joint Statistical Meetings, Toronto, Ontario.

June, 2007. Integrated Traffic Exposure Model Using GIS in Environmental Epidemiology. Presented at Society for Epidemiologic Research Meeting, Boston, Massachusetts.

March, 2009. A Population Model for the Effect of Cigarette Smoking on Lung Cancer. Invited presentation, Modeling Risk Prediction. Banff International Research Statistics, Banff, Alberta.

March, 2011. Estimation of air pollution dispersion from nonpoint sources. Spring Meeting, The Biometric Society, Eastern North American Region, Miami, Florida.

December, 2012. Spatial Models for Air Pollution and Health. University of Miami Spatial Statistics Conference, Miami, Florida.

January, 2013. Smoking History Generator. Tobacco Policy Modeling Workshop. Bethesda, Maryland.

April, 2013. Spatial Models for Traffic Related Air Pollution. New England Statistical Symposium, University of Connecticut, Storrs, Connecticut.

October, 2013. Modeling Past and Future Smoking Patterns in the US. Invited presentation, American Association for Cancer Research. National Harbor, Maryland.

December, 2013. Estimation of Parameters of Tobacco Use Behaviors. Invited presentation, Modeling and Statistical Methods for the Regulatory Assessment of Tobacco Products: A Public Workshop. Food and Drug Administration (FDA), Rockville, Maryland.

Professional Service:

Editorships

1984-1988	Associate Editor, <i>Biometrics</i> ,
1989-1998	Associate Editor, <i>American Journal of Epidemiology</i> ,
1990-2005	Editor, <i>Statistical Methods in Medical Research</i> ,
1999-present	Associate Editor, <i>Journal of Epidemiology and Biostatistics</i> ,

Committees

Consensus development conference on health implications of smokeless tobacco,
National Cancer Institute and National Institute of Dental Research, January, 1986

Epidemiology and Disease Control Study Section (EDC2), National Institutes of Health,
1986-1989

ENAR Regional Advisory Board, The Biometric Society, 1987-1990

Epidemiology Advisory Subcommittee, Oak Ridge Associated Universities, 1988-1993

Advisory Committee for the New York State Department of Health's Cancer Surveillance Improvement Initiative, 1998-2000

Data Safety Monitoring Board, Rare Diseases Clinical Research Network, 2006-present

Bibliography

Peer-reviewed original research

1. Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents. *Journal of the American Medical Association* 231: 583-608, 1975.
2. Holford, T.R. Life tables with concomitant information. *Biometrics* 32: 587-597, 1976.
3. Holford, T.R. and Hardy, R.J. A stochastic model for the analysis of age-specific prevalence curves in schistosomiasis. *Journal of Chronic Diseases* 29: 445-458, 1976.
4. Kelsey, J.L., Holford, T.R., White, C., Mayer, E.S., Kilty, S.E. and Acheson, R.M. Oral contraceptives and breast disease: An epidemiological study. *American Journal of Epidemiology* 107: 236-244, 1978.
5. Holford, T.R., White, C. and Kelsey, J.L. Multivariate analysis for matched case-control studies. *American Journal of Epidemiology* 107: 245-256, 1978.
6. Kelsey, J.L., Dwyer, T., Holford, T.R. and Bracken, M.B. Maternal smoking and congenital malformations: An epidemiological study. *Journal of Epidemiology and Community Health* 32: 102-107, 1978.
7. LiVolsi, V.A., Stadel, B.V., Kelsey, J.L., Holford, T.R. and White, C. Fibrocystic breast disease in oral contraceptive users: A histopathological evaluation of epithelial atypia. *New England Journal of Medicine* 299: 381-385, 1978.
8. Walter, S.D. and Holford, T.R. Additive, multiplicative, and other models for disease risks. *American Journal of Epidemiology* 108: 341-346, 1978.
9. Holford, T.R. The analysis of pair-matched case-control studies, a multivariate approach. *Biometrics* 34: 665-672, 1978.
10. Peduzzi, P., Holford, T.R. and Hardy, R.J. A computer program for life-table regression analysis and time-dependent covariates. *Computer Programs in Biomedicine* 9: 106-114, 1979.

11. Bracken, M.B. and Holford, T.R. Induced abortion and congenital malformations in offspring of subsequent pregnancies. *American Journal of Epidemiology* 109: 425-432, 1979.
12. Bracken, M.B., Holford, T.R., White, C. and Kelsey, J.L. Role of oral contraception in congenital malformations of offspring. *International Journal of Epidemiology* 7: 309-317, 1978.
13. Leaderer, B.P., Holford, Stolwijk, J.A. Relationship between sulfate aerosol and visibility. *Journal of the Air Pollution Control Association* 29: 154-157, 1979.
14. LiVolsi, V.A., Stadel, B.V., Kelsey, J.L. and Holford, T.R. Fibroadenoma in oral contraceptive users: A histopathologic evaluation of epithelial atypia. *Cancer* 44: 1778-1781, 1979.
15. Freeman, D.H. and Holford, T.R. Summary rates. *Biometrics* 36: 195-205, 1980.
16. Holford, T.R. The analysis of rates and of survivorship using log-linear models. *Biometrics* 36: 299-305, 1980.
17. Peduzzi, P.N., Hardy, R.J. and Holford, T.R. A stepwise variable selection procedure for non-linear regression models. *Biometrics* 36: 511-516, 1980.
18. Zito, R.A., Caride, V.J., Holford, T.R. and Zaret, B.L. Regional myocardial kinetics of lidocaine in experimental infarction: Modulation by regional blood flow. *American Journal of Cardiology* 47: 265-270, 1981.
19. Bracken, M.B. and Holford, T.R. Exposure to prescribed drugs in pregnancy and association with congenital malformations. *Obstetrics and Gynecology* 58: 336-344, 1981.
20. Hildreth, N.G., Kelsey, J.L., LiVolsi, V.A., Fischer, D.B., Holford, T.R., Mostow, E.D., Schwartz, P.E. and White, C. An epidemiologic study of epithelial carcinoma of the ovary. *American Journal of Epidemiology* 114: 398-405, 1981.
21. Kelsey, J.L., Fischer, D.B., Holford, T.R., LiVolsi, V.A. Mostow, E.D., Goldenberg, I.S. and White, C. Exogenous estrogens and other factors in the epidemiology of breast cancer. *Journal of the National Cancer Institute* 67: 327-333, 1981.
22. Hubert, H.B., Holford, T.R. and Kannel, W.H. Clinical characteristics and cigarette smoking in relation to prognosis of angina pectoris in Framingham. *American Journal of Epidemiology* 115: 231-242, 1982.
23. LiVolsi, V.A., Kelsey, J.L., Fischer, D.B., Holford, T.R., Mostow, E.D. and Goldenberg, I.S. Effect of age at first childbirth on risk of developing specific histologic subtype of breast cancer. *Cancer* 49: 1937-1940, 1982.

24. Kreiger, N., Kelsey, J.L., Holford, T.R. and O'Connor, T. An epidemiological study of hip fracture in postmenopausal women. *American Journal of Epidemiology* 116: 141-148, 1982.
25. Leaderer, B.P., Tanner, R.L. and Holford, T.R. Diurnal variations, chemical composition and relation to meteorological variables of the summer aerosol in the New York subregion. *Atmospheric Environment* 16: 2075-2087, 1982.
26. Holford, T.R. Covariance analysis for case-control studies with small blocks. *Biometrics* 38: 673-683, 1982.
27. Holford, T.R. The estimation of age, period and cohort effects for vital rates. *Biometrics* 39: 311-324, 1983.
28. Kelsey, J.L., LiVolsi, V.A., Holford, T.R., Fischer, D.B., Mostow, E.D., Schwartz, P.E., O'Connor, T. and White, C. A case-control study of cancer of the endometrium. *American Journal of Epidemiology* 116: 333-342, 1982.
29. Berkowitz, G.S., Holford, T.R. and Berkowitz, R.L. Effects of cigarette smoking, alcohol, coffee and tea consumption on preterm delivery. *Early Human Development* 7: 239-250, 1982.
30. Berkowitz, G.S., Kelsey, J.L., Holford, T.R. and Berkowitz, R.L. Physical activity and the risk of preterm spontaneous delivery. *Journal of Reproductive Medicine* 28: 581-588, 1983.
31. Goldacre, M.J., Holford, T.R. and Vessey, M.P. Cardiovascular disease and vasectomy: Findings from two epidemiological studies. *New England Journal of Medicine* 308: 805-808, 1983.
32. Berkowitz, G.S., Kelsey, J.L., LiVolsi, V.A., Holford, T.R., Merino, M.J., Ort, S., O'Connor, T.Z., Goldenberg, I.S. and White, C. Oral contraceptive use and fibrocystic breast disease among pre- and postmenopausal women. *American Journal of Epidemiology* 120: 87-96, 1984.
33. Hildreth, N.G., Kelsey, J.L., Eisenfeld, A.J., LiVolsi, V.A., Holford, T.R. and Fischer, D.B. Differences in breast cancer risk factors according to the estrogen receptor level of the tumor. *Journal of the National Cancer Institute* 70: 1027-1031, 1983.
34. Pastides, H., Kelsey, J.L., LiVolsi, V.A. Holford, T.R., Fischer, D.B. and Goldenberg, I.S. Oral contraceptive use and fibrocystic breast disease with special reference to its histopathology. *Journal of the National Cancer Institute* 71: 5-9, 1983.
35. Kelsey, J.L., Githens, P.B., Walter, S.D., Southwick, W.O., Weil, U., Holford, T.R., Ostfeld, A.M., Calogero, J.A., O'Connor, T. and White, A.A. An epidemiologic study of acute prolapsed cervical intervertebral disc. *Journal of Bone and Joint Surgery* 66-A: 907-914, 1984.

36. Kelsey, J.L., Githens, P.B., White, A.A., Holford, T.R., Walter, S.D., O'Connor, T., Ostfeld, A.M., Weil, U., Southwick, W.O. and Calogero, J.A. An epidemiologic study of lifting and twisting on the job and risk for acute prolapsed lumbar intervertebral disc. *Journal of Orthopaedic Research* 2: 61-66, 1984.
37. Kelsey, J.L., Githens, P.B., O'Connor, T., Weil, U., Calogero, J.A., Holford, T.R., White, A.A., Walter, S.D., Ostfeld, A.M. and Southwick, W.O. Acute prolapsed lumbar intervertebral disc: An epidemiologic study with special reference to driving automobiles and cigarette smoking. *Spine* 9: 608-613, 1984.
38. Berkowitz, G.S., Kelsey, J.L., LiVolsi, V.A., Merino, M.J., Holford, T.R., Hildreth, N.G., Ort, S., O'Connor, T.Z. and White, C. Exogenous hormone use and fibrocystic breast disease by histopathologic component. *International Journal of Cancer* 34: 443-449, 1984.
39. Garlinghouse, L.E., Smith, A.L. and Holford, T. The biological relationship of mouse hepatitis virus (MHV) strains and interferon: *In Vitro* induction and sensitivities. *Archives of Virology* 82: 19-29, 1984.
40. Berkowitz, G.S., Kelsey, J.L., LiVolsi, V.A., Holford, T.R., Merino, M.J., Beck, G.J., Ort, S., O'Connor, T.Z. and White, C. Estrogen replacement therapy and fibrocystic breast disease in postmenopausal women. *American Journal of Epidemiology* 121: 238-245, 1985.
41. Pastides, H., Kelsey, J.L., Holford, T.R. and LiVolsi, V.A. An epidemiologic study of fibrocystic breast disease with reference to ductal epithelial atypia. *American Journal of Epidemiology* 121: 440-447, 1985.
42. Holford, T.R., Brown, S.E. and Knudson, D.L. Estimation of DNA fragment size and generation of DNA restriction endonuclease maps using linear models. *Journal of Virological Methods* 10: 117-126, 1985.
43. Roush, G.C., Schymura, M.J., Holford, T.R., White, C. and Flannery, J.T. Time period compared to birth cohort in Connecticut incidence rates for twenty-five malignant neoplasms. *Journal of the National Cancer Institute* 74: 779-788, 1985.
44. Roush, G.C., Schymura, M.J. and Holford, T.R. Risk for cutaneous melanoma in recent Connecticut birth cohorts. *American Journal of Public Health* 75: 679-682, 1985.
45. Berkowitz, G.S., Kelsey, J.L., LiVolsi, V.A., Holford, T.R., Merino, M.J., Ort, S., O'Connor, T.Z. and White, C. Risk factors for fibrocystic breast disease and its histopathologic components. *Journal of the National Cancer Institute* 75: 43-50, 1985.
46. Barnea, E.R., Holford, T.R. and McInnes, D.R.A. Long term prognosis of infertile couples with normal basic investigation -- Life table analysis. *Obstetrics and Gynecology* 66: 24-26, 1985.

47. Bracken, M.B., Bryce-Buchanan, C., Silten, R. and Holford, T. Menarcheal age and habitual miscarriage: Evidence for an association. *Annals of Human Biology* 12: 525-531, 1985.
48. Holford, T.R. An alternative approach to statistical age-period-cohort analysis. *Journal of Chronic Diseases* 38: 831-836, 1985.
49. Bracken, M.B., Hellenbrand, K.G., Holford, T.R. and Bryce-Buchanan, C. Low birthweight in pregnancies following induced abortion: No evidence for an association. *American Journal of Epidemiology* 123: 604-613, 1986.
50. Bracken, M.B., Bryce-Buchanan, C. Srisuphan, W., Holford, T.R., Silten, R. Risk of late first and second trimester miscarriage after induced abortion. *American Journal of Perinatology* 3: 84-91, 1986.
51. Todd, M.B., Portlock, C.S., Farber, L.R., Holford, T.R., and Bertino, J.R. Prognostic indicators in diffuse large-cell (histiocytic) lymphoma. *International Journal of Radiation Oncology Biology Physics* 12: 593-601, 1986.
52. Coustan, D.R., Reece, E.A., Sherwin, R.S., Rudolf, M.C.J., Bates, S.E., Sockin, S.M., Holford, T.R., Taborlane, W.V. A randomized clinical trial of the insulin pump vs intensinve conventional therapy in diabetic pregnancies. *Journal of the American Medical Association* 255: 631-636, 1986.
53. Yarkoni, S., Reece, E.A., Wan, M., Holford, T., Romero, R., Hobbins, J.C. Intrapartum fetal weight estimation: A comparison of three formulae. *Journal of Ultrasound Medicine* 5: 707-710, 1986.
54. Yarkoni, S., Reece, E.A., Holford, T., O'Connor, T.Z., Hobbins, J.C. Estimated fetal weight in the evaluation of growth in twin gestations: A prospective longitudinal study. *Obstetrics and Gynecology* 69: 636-639, 1987
55. Reece, E.A., Holford, T., Tuck, S., Bargar, M., O'Connor, T., and Hobbins, J.C. Screening for gestational diabetes: One-hour carbohydrate tolerance test performed by a virtually tasteless polymer of glucose. *American Journal of Obstetrics and Gynecology* 156: 132-134, 1987.
56. Roush, G.C., Schymura, M.J., Stevenson, J.M., and Holford, T.R. Time and age trends for sinonasal cancer in Connecticut incidence and U.S. mortality rates. *Cancer* 60: 422-428, 1987.
57. Reece, E.A., Moya, F., Yazigi, R., Holford, T., Duncan, C., Ehrenkranz, R.J. Persistent pulmonary hypertension: Assessment of Perinatal Risk Factors. *Obstetrics and Gynecology* 70: 696-700, 1987.
58. Wickramaratne, P.J., and Holford, T.R. Confounding in epidemiologic studies: The adequacy of the control group as a measure of confounding. *Biometrics* 43: 751-765, 1987.

59. Peduzzi, P., Holford, T., Detre, K., and Chan, Y.-K. Comparison of the logistic and Cox regression models when outcome is determined in all patients after a fixed period of time. *Journal of Chronic Diseases* 40: 761-767, 1987.
60. Eskenazi, B., Bracken, M.B., Holford, T.R., and Grady, J. Exposure to organic solvents and hypertensive disorders of pregnancy. *American Journal of Industrial Medicine* 14: 177-188, 1988.
61. Roush, G.C., Schymura, M.J., Holford, T.R. Patterns of invasive melanoma in the Connecticut Tumor Registry: Is the long-term increase real? *Cancer* 60: 2586-2595, 1988.
62. Reece, E.A., Coustan, D.P., Hayslett, J.P., Holford, T., Coulehan, J., O'Connor, T.Z. Diabetic nephropathy: Pregnancy performance and fetomaternal outcome. *American Journal of Obstetrics and Gynecology* 159: 56-66, 1989.
63. Wickramaratne, P.J., Weissman, M.M., Leaf, P.J., Holford, T.R. Age, period and cohort effects on the risk of major depression: Results from five United States Communities. *Journal of Clinical Epidemiology* 42: 333-343, 1989.
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65. Holford, T.R., Bracken, M.B., and Eskenazi, B. Log-linear models for the analysis of matched cohort studies. *American Journal of Epidemiology* 130: 1247-1253, 1989.
66. Bracken, M.B., Hellenbrand, K.G., and Holford, T.R. Conception delay after oral contraceptive use: The effect of estrogen dose. *Fertility and Sterility* 53: 21-27, 1990.
67. Wickramaratne, P.J., and Holford, T.R. Confounding in epidemiologic studies, Response to Reader Reactions. *Biometrics* 45: 1319-1322, 1989.
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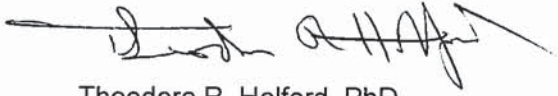
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I certify under penalty of perjury that the statements in my expert report dated June 1, 2017 are true and correct. Executed on Sept. 11, 2017.

A handwritten signature in black ink, appearing to read 'Theodore R. Holford', with a long horizontal line extending to the left and a sharp upward stroke at the end.

Theodore R. Holford, PhD

EXHIBIT DX2

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 1

UNITED STATES DISTRICT COURT
DISTRICT of MINNESOTA

In Re:

Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION of THEODORE R. HOLFORD

VOLUME I, PAGES 1 - 386

JULY 18, 2017

(The following is the deposition of THEODORE
R. HOLFORD, taken pursuant to Notice of Taking
Deposition, via videotape, at the Marriott Hartford
Downtown, 200 Columbus Boulevard, Hartford,
Connecticut, commencing at approximately 9:20 o'clock
a.m., July 18, 2017.)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 2			Page 4		
1	APPEARANCES:		1	9	Article, Association of Airborne
2	On Behalf of the Plaintiffs:		2		Microorganisms in the Operating
3	Michael A. Sachet and Jan M. Conlin		3		Room With Implant Infections: A
4	CIRESI CONLIN L.L.P.		4		Randomized Controlled Trial, by
5	225 South 6th Street, Suite 4600		5		Darouiche, et al 54
6	Minneapolis, Minnesota 55402		6	10	Proceedings of the International
7	On Behalf of Defendants:		7		Consensus Meeting on Peri-
8	Corey L. Gordon		8		prosthetic Joint Infection 67
9	BLACKWELL BURKE P.A.		9	11	Van Duren March 7, 2017
10	432 South Seventh Street, Suite 2500		10		transcript excerpt 77
11	Minneapolis, Minnesota 55415		11	12	Article, Convection warmers --
12	ALSO APPEARING:		12		a possible source of contamination
13	Ronald M. Huber, Videotechnician		13		in laminar airflow operating
14			14		theatres? by Tumia, et al 80
15			15	13	Article, Forced-air warming
16			16		and ultra-clean ventilation do
17			17		not mix, by McGovern, et al 94
18			18	14	Computer printout, AUGUSTINE_
19			19		0005193-487 104
20			20	15	Albrecht October 7, 2016
21			21		deposition excerpt 123
22			22	16	LogisticRegression analysis,
23			23		Albrecht, March 11, 2016,
24			24		Albrecht_0002275-8 135
25			25	17	Gmail string 140
Page 3			Page 5		
1	I N D E X		1	18	Computer printout 148
2	EXHIBITS	PAGE MARKED	2	19	Article, Return to theatre
3	Ex 1 Expert Report of Theodore R.		3		following total hip and knee
4	Holford, PhD 11		4		replacement, before and after
5	2 Holford curriculum vitae 11		5		the introduction of rivaroxaban,
6	3 Expert report of Jonathan M.		6		by Jensen, et al 179
7	Samet 11		7	20	Fisher's exact test of
8	4 Albrecht October 7, 2016		8		independence article 198
9	deposition excerpts 23		9	21	Article, Levels of Household
10	5 Augustine Biomedical + Design		10		Mold Associated with Respiratory
11	Research and Development		11		Symptoms in the First Year of
12	Report, 9/14/2007 24		12		Life in a Cohort at Risk for
13	6 Article, Forced-Air Warming		13		Asthma, by Gent, et al 201
14	Design: Evaluation of Intake		14	22	Chi-square test of goodness-
15	Filtration, Internal Microbial		15		of-fit article 208
16	Buildup, and Airborne-		16	23	Graph, 3M00554267 229
17	Contamination Emissions, by		17	24	Article, Infection Control in
18	Reed, et al 28		18		Orthopaedic Surgery 249
19	7 Article, Predicting bacterial		19	25	Article, Implementing effective
20	populations based on airborne		20		SSI surveillance, by Gillson
21	particulates: A study performed		21		et al 251
22	in nonlaminar flow operating		22	26	Article, Confounding in
23	rooms during joint arthroplasty		23		Epidemiologic Studies, by
24	surgery, by Stocks, et al 46		24		Greenland, et al 283
25	8 E-mail string, 3MBH00050770-1 50		25	27	Article, Statistical Methods in

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<p style="text-align: right;">Page 6</p> <p>1 Cancer Research, by Breslow et 2 al 297 3 28 Article, Forced-air warming 4 discontinued: periprosthetic 5 joint infection rates drop, 6 by Augustine 329 7 29 Jonathan Borak expert report 362 8 30 Record of Proceedings, Health- 9 care Infection Control Practices 10 Advisory Committee, November 11 5-6, 2015 368 12 31 Record of Proceedings, Health- 13 care Infection Control Practices 14 Advisory Committee, March 31, 15 2016 376 16 32 Arizant forced-air warming and 17 SSI prevention: Talking points 18 for sales, 3MBH00001336-7 381 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 8</p> <p>1 biostatistics? 2 A. Yes. 3 Q. Epidemiology? 4 A. It was in regard to a statistical review 5 that I did of an epidemiology calculation paper -- or 6 chapter of a book, actually. 7 Q. What was the chapter of that book? 8 A. It was a chapter dealing with lung cancer 9 trends, and they were relating it to smoking. 10 Q. Okay. And were the studies that you relied 11 on in that chapter of the book observational studies? 12 A. Yes. 13 Q. What -- 14 How many studies were there? 15 A. I don't recall. It was a -- quite a long -- 16 quite a long time ago. I think some of it was 17 population data as I recall, but it's been -- been 18 quite a long time; I've forgotten the details of it. 19 Q. And who retained you to provide expert 20 testimony in that litigation? 21 A. It was the tobacco companies. They -- 22 they -- I was -- I -- they de -- deposed me. They 23 subpoenaed me and wanted me to be a witness. 24 MR. GORDON: I -- I think he's not 25 understanding -- he's not tracking what you mean by</p>
<p style="text-align: right;">Page 7</p> <p>1 PROCEEDINGS 2 (Witness sworn.) 3 THEODORE R. HOLFORD 4 called as a witness, being first duly sworn, 5 was examined and testified as follows: 6 ADVERSE EXAMINATION 7 BY MR. SACCHET: 8 Q. Good afternoon, Professor Holford. My name 9 is Michael Sacchet and I represent the plaintiffs in 10 this litigation. 11 Could you please state your full name for 12 the record. 13 A. Theodore Richard Holford. 14 Q. And Professor Holford, have you had your 15 deposition taken before? 16 A. Not on this. 17 Q. In the past? 18 A. Yes, I have. 19 Q. What was the subject matter of that 20 deposition? 21 A. Cigarette smoking. 22 Q. How long ago? 23 A. Ooh. It was probably eight years ago, 24 something like that, eight, 10 years ago. 25 Q. And were you called to offer opinion as to</p>	<p style="text-align: right;">Page 9</p> <p>1 "retained." 2 MR. SACCHET: Yeah. I'll -- I'll clarify 3 the question. 4 MR. GORDON: Thank you. 5 Q. So the tobacco industry was examining 6 adversely or -- 7 A. Yes. 8 Q. Okay. And who were you -- 9 A. Well I -- yeah, I guess it was -- 10 Yeah. They called me and it was because I 11 had been critical of one of the papers -- one of the 12 chapters at the time, and that's why I was deposed. 13 Q. What were you critical about? 14 A. Details on their analysis. 15 Q. And their analysis is that there was not 16 causation with respect to tobacco use and lung cancer? 17 A. No. No. It was -- 18 The analysis had to do with looking at 19 trends, lung cancer trends -- 20 Q. Okay. 21 A. -- and -- and disease trends, and that's an 22 area that's been of particular statistical interest. 23 Q. These were time trends? 24 A. Yes. 25 Q. Any other times in which you've offered</p>

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<p style="text-align: right;">Page 10</p> <p>1 expert testimony, whether it be in a deposition or 2 through an expert report? 3 A. No. 4 Q. You're familiar with the rules of 5 deposition? 6 A. I think so. 7 Q. I'll just quickly review them so we're on 8 the same page. 9 As you know, I'll be asking you questions 10 and you'll be answering un -- them under oath. If you 11 don't understand a question, let me know and I'll do 12 my best to clarify. For purposes of the court 13 reporter, it's best if you allow me to finish my 14 question before you attempt to answer it so that we 15 have a clear record. And last and perhaps most 16 importantly, if you could answer all questions 17 verbally as opposed to nodding or shaking your head so 18 we have an opportunity to record your answer. Is that 19 agreeable? 20 A. Yes. 21 Q. In this litigation you've drafted a report; 22 correct, professor? 23 A. That's correct. 24 Q. We'll be marking this report as Exhibit 1. 25 I see you have one in front of you, but for the sake</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. The report that you have filed in this case 2 responds to Dr. Samet's report; is that correct, Dr. 3 Holford? 4 A. Yes, that's correct. 5 Q. And that appears to be a full version of Dr. 6 Samet's report? 7 A. It appears to be, yes. 8 Q. Based on your curriculum vitae, I understand 9 that you have a B.A. in mathematics and chemistry; is 10 that correct? 11 A. That's correct. 12 Q. And you earned those degrees from Andrews 13 University? 14 A. Yes. 15 Q. Where is Andrews? 16 A. Berrian Springs, Michigan. 17 Q. Is that where you're from? 18 A. No. 19 Q. Why did you decide to go there? 20 A. Well my parents basically just made it clear 21 that that's where they wanted me to go. 22 Q. Okay. And you subsequently earned a Ph.D. 23 from Yale University in biometrics; correct? 24 A. That's correct. 25 Q. And biometrics is the application of</p>
<p style="text-align: right;">Page 11</p> <p>1 of the exhibit, please determine whether it is a full 2 and accurate copy of the report you have submitted in 3 this case. 4 (Exhibit 1 was marked for 5 identification.) 6 MR. GORDON: This is just his report without 7 the CV? 8 MR. SACCHET: Yeah. I'll get there. 9 MR. SACCHET: And attached to your -- 10 Well I'll let you look at it first. 11 (Exhibit 2 was marked for 12 identification.) 13 A. Yes, it appears to be complete. 14 Q. And you also attached your curriculum vitae 15 to your report; correct? 16 A. Yes. 17 Q. And is that an accurate copy of your CV from 18 what you can tell? 19 A. It appears to be so, yes. 20 MR. SACCHET: And as another housekeeping 21 matter, we are going to mark Dr. Samet's report as 22 Exhibit 3. 23 (Exhibit 3 was marked for 24 identification.) 25 BY MR. SACCHET:</p>	<p style="text-align: right;">Page 13</p> <p>1 statistical methods to biological data? 2 A. Basically, yes. 3 Q. So in large part the focus is on statistics; 4 correct? 5 A. Yes. 6 Q. What is the relationship of biostatistics to 7 epidemiology? 8 A. Epidemiologists use biostatistics a lot in 9 their -- in their research, so there's often a 10 collaborative arrangement between epidemiologists 11 and -- and -- and statisticians. 12 Q. They are two separate fields though; 13 correct? 14 A. They are, yes. 15 Q. You do not have a degree in epidemiology; 16 correct? 17 A. No. 18 Q. You do not have clinical training in 19 epidemiology? 20 A. Most epidemiologists are not clinicians -- 21 or many epidemiologists are not, so no, that's 22 correct. 23 Q. Some are; correct? 24 A. Some are. 25 Q. Dr. Samet is; correct?</p>

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<p style="text-align: right;">Page 14</p> <p>1 A. Yes.</p> <p>2 Q. You are not a medical doctor.</p> <p>3 A. No, I am not.</p> <p>4 Q. And you are not an anesthesiologist.</p> <p>5 A. No.</p> <p>6 Q. And you do not have experience in</p> <p>7 arthroplasty; correct?</p> <p>8 A. No.</p> <p>9 Q. The majority of your professional career has</p> <p>10 been at Yale University in a research and teaching</p> <p>11 capacity; correct?</p> <p>12 A. Yes, that's correct.</p> <p>13 Q. I saw some examples on your curriculum vitae</p> <p>14 in which you've gone elsewhere, I think Oxford</p> <p>15 University and maybe a few other locations, to do</p> <p>16 other work. Could you describe those -- those</p> <p>17 opportunities briefly?</p> <p>18 A. Yes. At Oxford I was on -- I had a</p> <p>19 sabbatical year which I took at Oxford University.</p> <p>20 Q. And what did you do during the sabbatical</p> <p>21 year?</p> <p>22 A. I -- I did research, I taught a class, and</p> <p>23 I -- I basically worked on my research.</p> <p>24 Q. Okay. With respect to the research that you</p> <p>25 have published, you have focused on cancer; correct?</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Any other topics of focus?</p> <p>2 A. Oh, I've occasionally done things related to</p> <p>3 in -- infectious diseases. My dissertation research</p> <p>4 was on schistosomiasis and statistical modeling for</p> <p>5 that. I've done work with a clinical trial on spinal</p> <p>6 cord injuries, the treatment for spinal cord injury.</p> <p>7 Q. Okay.</p> <p>8 A. Lots of work in cancer of course,</p> <p>9 various -- various aspects of it. Currently, I'm</p> <p>10 doing a lot of work on population models for cancer,</p> <p>11 mostly lung cancer, but --</p> <p>12 Q. Okay.</p> <p>13 A. -- yeah, it's related.</p> <p>14 Q. You have not researched computational fluid</p> <p>15 dynamics; correct?</p> <p>16 A. No.</p> <p>17 Q. You have not performed research on operating</p> <p>18 room airflow; correct?</p> <p>19 A. On operating --</p> <p>20 On what?</p> <p>21 Q. Room airflow.</p> <p>22 A. No.</p> <p>23 Q. How about filtration of operating rooms?</p> <p>24 A. No.</p> <p>25 Q. What about filtration of medical devices?</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I've done a fair amount on cancer. It's not</p> <p>2 the only thing I've worked on, but yes.</p> <p>3 Q. Other topics that I noticed when I reviewed</p> <p>4 some of your literature were articles on contraception</p> <p>5 and pregnancy.</p> <p>6 A. That was early on. It was -- it was more on</p> <p>7 looking at the potential side effects of contraceptive</p> <p>8 use.</p> <p>9 Q. What would you say are the primary topics of</p> <p>10 your research in addition to cancer, smoking,</p> <p>11 contraception and pregnancy?</p> <p>12 A. Air pollution is another thing that I've</p> <p>13 worked on. Yeah, air pollution and childhood asthma.</p> <p>14 Q. Okay. So I've read a couple of the articles</p> <p>15 and what I can tell is that you have researched the</p> <p>16 impact of particulates on respiratory disease;</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Have you ever researched the impact of</p> <p>20 particulates on other types of disease?</p> <p>21 A. Not that I recall.</p> <p>22 Q. So it's limited to the impact on respiratory</p> <p>23 diseases.</p> <p>24 A. Yes, particularly childhood -- childhood</p> <p>25 asthma.</p>	<p style="text-align: right;">Page 17</p> <p>1 A. No.</p> <p>2 Q. What about anesthesia?</p> <p>3 A. No.</p> <p>4 Q. Microbiology?</p> <p>5 A. No.</p> <p>6 Q. Orthopedics?</p> <p>7 A. No.</p> <p>8 Q. So I assume that means no for deep joint</p> <p>9 infection.</p> <p>10 A. Yes.</p> <p>11 Q. Are you offering testimony as to any of</p> <p>12 those subject matters?</p> <p>13 A. I'm offering testimony on statistical</p> <p>14 aspects that relate to the -- the Bair Hugger. I</p> <p>15 don't know if you think that's related or not.</p> <p>16 Q. But as to the core topic of those subject</p> <p>17 matters --</p> <p>18 A. Those subjects, no.</p> <p>19 Q. -- you are not opining --</p> <p>20 A. No, I am not.</p> <p>21 Q. -- about them discretely; correct?</p> <p>22 A. That's correct.</p> <p>23 Q. So you are not responding to the reports of</p> <p>24 Dr. Said Elghobashi, for example, --</p> <p>25 A. No.</p>

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<p style="text-align: right;">Page 18</p> <p>1 Q. -- which is a report on computational fluid 2 dynamics. 3 A. Yeah. No, I am not. 4 Q. And you are not responding to Dr. Jarvis's 5 report from a microbiology standpoint; correct? 6 A. Not from a microbiology standpoint. 7 Q. Is your testimony limited to the McGovern 8 study? 9 A. Primarily, yes. 10 Q. What do you mean by "primarily?" 11 A. Well that -- that was the focus of what I 12 was looking at, was the McGovern study. 13 Q. Your report says that "This report is a 14 review of the observational study of risk for deep 15 joint infection following the use of Bair Hugger 16 warming device during hip and knee replacement 17 surgery..." correct? 18 A. Yes. 19 MR. GORDON: To clarify, subsequent to his 20 report and -- and in light of Dr. Samet's reliance on 21 the newly published Augustine paper, we've asked him 22 to take a look at that. 23 Q. To the extent that Dr. Samet's causal 24 inference depends on factors outside of the McGovern 25 study, you do not have an expertise to opine on that</p>	<p style="text-align: right;">Page 20</p> <p>1 opinions to the extent that they rely on a clinical 2 perspective of epidemiology; correct? 3 A. Not the clinical perspective, that's right. 4 Q. To the extent Dr. Samet's opinions rely on 5 his experience with filtration, you are not responding 6 to those opinions; are you? 7 A. No. 8 Q. And to the extent that Dr. Samet relies on 9 his experience in particulate matter, you're not 10 responding to those opinions; are you? 11 A. No. 12 Q. You nonetheless opine, however, that 13 particles are simply an intermediate proxy for deep 14 joint infection; correct? 15 A. I'm sorry, could you repeat that? 16 Q. Your report states that particles are at 17 most an intermediate outcome that has not been shown 18 to directly relate to the outcome of interest, deep 19 joint infection; correct? 20 A. Yes. 21 Q. If you do not have the expertise that Dr. 22 Samet has in airborne particulate matter, on what 23 basis are you making that conclusion? 24 MR. GORDON: Object to the form of the 25 question.</p>
<p style="text-align: right;">Page 19</p> <p>1 subject matter; correct? 2 A. Yes. 3 Q. To the extent that Dr. Samet's report 4 includes his experience as a medical doctor, you do 5 not have expertise to respond to those opinions; 6 correct? 7 A. Not the particular ones that related to the 8 medical opinions, yes. 9 Q. To the extent that Dr. Samet's report relies 10 on his training in anesthesiology, you do not have 11 expertise to respond to those conclusions; correct? 12 A. That's correct. 13 Q. To the extent that Dr. Samet's opinions 14 hinge on his experience as a clinical epidemiologist, 15 you do not have experience to respond to those 16 opinions; correct? 17 A. I have not been a clinical epidemiologist, 18 no. I have worked -- worked with a lot of others that 19 have done, you know, clinical epidemiology work so 20 I've been involved with people doing that kind of 21 work, but primarily from a statistical perspective. 22 Q. So you don't have expertise to respond to 23 the clinical side of epidemiology; correct? 24 A. Correct. 25 Q. So you are not responding to Dr. Samet's</p>	<p style="text-align: right;">Page 21</p> <p>1 A. I'm sorry, could you repeat the question? 2 Q. To the extent that you have concluded that 3 particles are at most an intermediate outcome that has 4 not been shown to relate to the outcome of interest, 5 deep joint infection, on what basis are you making 6 that conclusion? 7 A. I'm basing that on the -- on the -- some of 8 the manuscripts related -- related to that and some of 9 the other testimony and things that I've related to 10 that or related to the pub -- in terms of the Bair 11 Hugger. 12 Q. Which manuscripts? 13 A. I'm -- let's see. I've -- 14 There's some of the work that the 15 Albright -- Albrecht, is that -- the person that works 16 with Augustine, and some of -- some of that work where 17 they were -- where they were trying to look at the -- 18 the output from the device and look at the infection, 19 look -- looking for organisms deposited on agar plates 20 from -- from that, it was one of those papers. 21 I've -- I've forgotten exactly which -- which the 22 author was, but I re -- remember that recollection, so 23 that's the basis of that. 24 Q. And that's your only basis? 25 A. That's primarily my only basis, yes.</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. You know that Mr. Albrecht is not a 2 microbiologist; right? 3 A. Yes. 4 Q. You have not reviewed any published studies 5 regarding the link between particles and bacteria and 6 deep joint infection? 7 A. No, that's not been -- been my primary 8 focus. 9 Q. So with respect to the conclusion that 10 particles are at most an intermediate outcome that has 11 not been shown to directly relate to the outcome of 12 interest, deep joint infection, you are solely relying 13 on Albrecht's manuscript. 14 A. His manuscript and his testimony where he 15 was describing how he was trying to deposit organisms 16 onto agar plates and -- and that kind of stuff. He 17 was -- 18 That was not successful, as I recall. 19 Q. And you're referring to his deposition 20 transcript; correct? 21 A. Yes. 22 Q. Have you listed everything that you have 23 relied on on page 14 of your report, which outlines 19 24 different sources? 25 A. I think so. That's the -- that's basically</p>	<p style="text-align: right;">Page 24</p> <p>1 "...Exhibit 1 is a report for -- from certain work -- 2 research activities that were done at the Regina 3 Surgery Center..." Do you see that, -- 4 A. Yes. 5 Q. -- Professor Holford? 6 A. Uh-huh. 7 Q. Is this one of the exhibits that you rely on 8 with respect to Mr. Albrecht's testimony regarding 9 bacteria? 10 MR. GORDON: Do you have that exhibit? 11 MR. SACCHET: I do. 12 A. I -- I think this is -- this is -- this is 13 the one, yes. 14 Q. Did you rely on the deposition testimony or 15 the exhibits to the deposition when you concluded that 16 particles are at most an indeterminate outcome? 17 MR. GORDON: Object to the form of the 18 question. 19 A. I was -- I was relying primarily on the -- 20 on the deposition. 21 Q. Have you seen the Exhibit 1 that was marked 22 at this deposition? 23 A. I -- I don't recall. 24 (Exhibit 5 was marked for 25 identification.)</p>
<p style="text-align: right;">Page 23</p> <p>1 what I relied on in writing this, yes. 2 Q. Have you reviewed anything since you filed 3 your report until today in addition to those sources? 4 A. I reviewed the recent paper by Augustine 5 and, let's see, what else? That's most of what I -- 6 what I have -- have re -- reviewed. I -- I saw some 7 of -- a small piece of Augustine's dep -- deposition, 8 and that's -- that's about it. 9 Q. Okay. I'm going to circle back to 10 Albrecht's deposition testimony with respect to the 11 testing that he did on particles and bacteria. 12 (Exhibit 4 was marked for 13 identification.) 14 BY MR. SACCHET: 15 Q. This is an excerpt of Mr. Albrecht's 16 deposition; correct? 17 A. Yes. 18 Q. And if you could turn to page seven in the 19 bottom right-hand corner, or internal page 23 in the 20 top right-hand corner -- 21 MR. GORDON: Did you mark this? 22 THE REPORTER: Yes. 23 MR. SACCHET: I did. 24 THE REPORTER: That's four. 25 Q. -- and you'll see line 23 of page 23 says,</p>	<p style="text-align: right;">Page 25</p> <p>1 BY MR. SACCHET: 2 Q. Does this document refresh your recollection 3 as to whether you have reviewed Exhibit 1 of the 4 Albrecht deposition? 5 A. No. I did not see this document. 6 Q. You've never seen the document before. 7 A. No. 8 Q. So you only relied on the deposition 9 transcript in determining that particles are at most 10 an indeterminate outcome of deep joint infection. 11 MR. GORDON: Object to the form of the 12 question, assumes facts not in evidence. 13 A. I think what I'm saying is that this -- this 14 document is not -- was -- was not what I had 15 considered. 16 Q. Did you review any of the exhibits that were 17 marked at the Albrecht deposition with respect to the 18 testimony regarding testimony of particulates versus 19 bacteria? 20 A. I didn't review the exhibits, no. 21 Q. Okay. Let's go back to the transcripts 22 then. And I believe your conclusion about particles 23 being related to bacteria can be found on page 19 in 24 the bottom right-hand corner, or page 73, which is the 25 internal page.</p>

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<p style="text-align: right;">Page 26</p> <p>1 MR. GORDON: What page?</p> <p>2 MR. SACCHET: Nineteen TSG, internal 73.</p> <p>3 MR. GORDON: Oh, I see. All right.</p> <p>4 Q. And line 16 states, "Okay. Did -- so you --</p> <p>5 you found that there were particles of various sizes,</p> <p>6 various counts coming out of the Bair Hugger?"</p> <p>7 Response: "Yes, we did.</p> <p>8 "Question: But you really didn't find much</p> <p>9 in the way of bacteria coming out?"</p> <p>10 Response: "We did not."</p> <p>11 A. Yes.</p> <p>12 Q. Did you review the other sections of this</p> <p>13 deposition transcript aside from that conclusion?</p> <p>14 A. That's most of what I -- what I noticed in</p> <p>15 that report, yes.</p> <p>16 Q. Okay. If I could draw your attention to the</p> <p>17 Exhibit 5, which is the report that is cited in this</p> <p>18 deposition transcript, the last page, page 12, notes</p> <p>19 that, in the first bullet point, "...testing done in</p> <p>20 our lab rated the 505 intake filter at roughly 94</p> <p>21 percent;" correct?</p> <p>22 A. Yes, that's what it says.</p> <p>23 Q. Do you have any reason to doubt that the</p> <p>24 testing that was done with respect to Mr. Albrecht's</p> <p>25 testimony in this transcript involved a device</p>	<p style="text-align: right;">Page 28</p> <p>1 (Exhibit 6 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. If you could turn your attention to the</p> <p>5 column in the right-hand side on page one, the first</p> <p>6 full sentence starts with "Prior research..." Do you</p> <p>7 see that, Dr. Holford? On the first page, right-hand</p> <p>8 column.</p> <p>9 Text, not abstract.</p> <p>10 A. "Prior research," is that what you said?</p> <p>11 Q. Yes.</p> <p>12 A. Yeah. Okay.</p> <p>13 Q. "Prior research has rated the intake</p> <p>14 filtration efficiency of legacy FAW devices (Bair</p> <p>15 Hugger 505, Arizant Healthcare) at 93.8 percent for an</p> <p>16 'older' filter model in clinical use (200708C) and</p> <p>17 61.3 percent for a 'newer' filter model (200708D)</p> <p>18 scheduled to replace the older filter in clinical</p> <p>19 use." Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Does that make clear that there are two</p> <p>22 different filtration capacities?</p> <p>23 A. Yes, it does.</p> <p>24 Q. And the older filter that we're talking</p> <p>25 about has been denominated as the Bair Hugger 505;</p>
<p style="text-align: right;">Page 27</p> <p>1 different than the 505?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, lack of foundation.</p> <p>4 A. I have no idea what they were using. I</p> <p>5 mean --</p> <p>6 Yeah, I don't -- I don't know.</p> <p>7 Q. This exhibit makes clear that testing was</p> <p>8 done on the 505; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Are you aware that the model 505 uses a</p> <p>11 different filter than the Bair Hugger model 750 and</p> <p>12 775?</p> <p>13 A. No. I -- I'm not familiar with -- with</p> <p>14 which filters are used on them.</p> <p>15 Q. You cited the Reed article in your reference</p> <p>16 list; correct?</p> <p>17 A. Yes.</p> <p>18 Q. Did you review that article?</p> <p>19 A. I did look at that article, yes.</p> <p>20 Q. So you reviewed the article but you're not</p> <p>21 aware that there are two different filter efficiencies</p> <p>22 for the model 505 versus the model 750.</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 A. I was not reviewing the particular filters.</p>	<p style="text-align: right;">Page 29</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And below that, do you see the reference to</p> <p>4 Bair Hugger 750 in the next paragraph?</p> <p>5 A. Yes.</p> <p>6 Q. Are you now aware that there are two</p> <p>7 different filtration efficiencies?</p> <p>8 A. Yes.</p> <p>9 Q. If we could now turn back to the deposition</p> <p>10 transcript, which has been marked as Exhibit 4, and if</p> <p>11 you could turn to page 40, internal page 40, and line</p> <p>12 nine states, "We were assessing filtration efficiency</p> <p>13 and that dealt with particles on the in and out</p> <p>14 stream, because it's very important in case there are</p> <p>15 resident airborne microbes that could be sucked in and</p> <p>16 delivered through." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Based on that testimony and the documents we</p> <p>19 have reviewed, is it clear to you that Mr. Albrecht</p> <p>20 was conducting testing on the filter of the model 505?</p> <p>21 MR. GORDON: Object to the form of the</p> <p>22 question, lacks foundation.</p> <p>23 A. I'm not -- I guess I'm not really under --</p> <p>24 understanding if he's testing the filter or if he's</p> <p>25 testing -- you know, filter per se, because as I -- as</p>

8 (Pages 26 to 29)

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<p style="text-align: right;">Page 30</p> <p>1 I understand it, there's a whole mechanism that's -- 2 that's involved here. It's not just the filter. 3 Q. Okay. Let's look at what's been marked as 4 Exhibit 5, the report. 5 A. Okay. 6 Q. Do you see point four? 7 A. Yeah. 8 Q. Says, "Impaction: Impaction sampling will 9 be performed on the air stream in the distal region of 10 the hose on a non-specific growth media." 11 A. Okay. 12 Q. Are you aware that in order to test whether 13 anything would come out of the hose, it would first 14 need to travel through the filter of the device? 15 A. Yes. 16 MR. GORDON: Object to the form of the 17 question, lack of foundation. 18 Q. You are aware of that. 19 A. It would have -- 20 It would apparently go through -- through 21 the filter, yes. 22 Q. So with respect to this testing, the model 23 505 was tested to determine whether particles moved 24 through the filter and out of the distal hose; 25 correct?</p>	<p style="text-align: right;">Page 32</p> <p>1 have any reason to doubt -- 2 MR. GORDON: But that -- that's true, 3 counsel, but you're -- you've jumped ahead about 50 4 pages in the deposition, and I -- I was there, I took 5 it. There were other exhibits marked. We were not 6 talking exclusively about Exhibit 1, and I think 7 that's really unfair. 8 MR. SACCHET: There's one other exhibit I 9 can maintain that regards the testimony that Mr. 10 Albrecht gave in that deposition, and that has been 11 marked as Albrecht Exhibit 3. Is that what you're 12 referring to, Mr. Gordon? 13 MR. GORDON: I don't know. You'd have to 14 show it to me. But there was -- it wasn't just the 15 Regina testing; there were three different tests. 16 Q. Okay. So let's just look at the deposition 17 testimony if you're unwilling to conclude that 18 Exhibit 1 is -- is the foundation for the testimony 19 that Mr. Albrecht provided. 20 On line 36 of the deposition transcript -- 21 or excuse me, page 36, if you could turn to that, Dr. 22 Holford, line five states: 23 "So you were looking for particles coming 24 out, that were being blown out of the Bair Hugger -- 25 "Uh-huh."</p>
<p style="text-align: right;">Page 31</p> <p>1 MR. GORDON: Same object -- same objection. 2 A. It would be doing that, but I've already 3 said that this -- this particular document was not 4 something that I -- I was reviewing. 5 Q. Well this is a document that's referenced in 6 the deposition of the testing that was done with 7 respect to what you're relying on; correct? 8 MR. GORDON: Object to the form of the 9 question, and also misconstrues the evidence. 10 A. What I -- what I think I've -- what I said 11 was -- is I looked at the deposition, I was -- I did 12 not refer to the -- directly to the -- to all -- to 13 all of the exhibits in it. 14 Q. So now that we're reviewing the exhibit, 15 that is a document -- the testing that was performed 16 by Mr. Albrecht, does that enlighten your viewpoint? 17 MR. GORDON: Well object to the form of the 18 question. Counsel, you've shown him one exhibit. 19 There were multiple exhibits marked in the 20 August -- at the Albrecht deposition. 21 Q. We can go back to the line in the exhibit 22 which we reviewed just a moment ago on page -- 23 internal page 23 that says, "...Exhibit 1 is a report 24 for -- from certain work -- research activities that 25 were done at the Regina Surgery Center..." Do you</p>	<p style="text-align: right;">Page 33</p> <p>1 Do you see that? 2 A. Yes. 3 Q. And the subsequent lines say: 4 "Question: -- that was the particle 5 counting? 6 "But with the impaction counting you were 7 looking to see if there were any actual bacteria that 8 were being blown out of the Bair Hugger? 9 "Correct." 10 A. Yes. 11 Q. Does that provide an example of the 12 testimony that you relied on in determining that Mr. 13 Albrecht's testing involved whether Bair Hugger -- 14 whether bacteria came out of the Bair Hugger? 15 A. Are you asking for -- 16 I don't understand the -- the question. Are 17 you asking was he looking at any -- whether or not any 18 particles were coming out of the Bair Hugger -- 19 Q. Does this -- 20 A. -- or are you asking whether there were 21 bacteria that were coming out of the Bair Hugger? 22 Q. Was Mr. Albrecht trying to determine that 23 bacteria were being blown out of the Bair Hugger? 24 A. He was trying to do that, yes. 25 Q. Okay. Do you know how he was trying to</p>

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<p style="text-align: right;">Page 34</p> <p>1 sample whether bacteria were coming out of the Bair 2 Hugger? 3 A. As I've said, this is not really my area, 4 but I -- my understanding was the -- that the kinds of 5 things that he was doing is blowing it on agar plates 6 and things like that. 7 Q. Do you know what he was blowing it out of? 8 A. The Bair Hugger, this -- this device. 9 Q. Do you know whether he was blowing it out of 10 the hose or out of the blanket? 11 A. I -- I -- 12 It's been a while since I read that. I 13 think it was out of the -- out of the blanket, but I 14 may be -- I may be -- 15 I don't recall -- really recall. 16 Q. Do you know whether bacteria was tested at 17 the surgical site? 18 A. At -- 19 During the surgery? 20 Q. Was bacteria being collected at the surgical 21 site? 22 MR. GORDON: At what point? 23 THE WITNESS: At what point? 24 MR. SACCHET: During the testing. 25 MR. GORDON: Which -- which testing?</p>	<p style="text-align: right;">Page 36</p> <p>1 MR. GORDON: Object to the form of the 2 question. 3 A. I think he was trying to, yeah, culture 4 that -- what was coming out of the hose, yes. 5 Q. Mr. Albrecht did not conduct testing to 6 determine whether disruption in airflow currents in 7 the operating room caused bacteria to enter the 8 surgical site; correct? 9 MR. GORDON: Object to the form of the 10 question, assumes facts not in evidence, lack of 11 foundation. 12 A. Yeah. I'm not under -- really understanding 13 what your question is. I -- 14 Q. You reviewed Mr. Albrecht's transcript; -- 15 A. Yes. 16 Q. -- correct? 17 Did you see any mention in the transcript as 18 to whether Mr. Albrecht did any testing beyond simply 19 sampling bacteria out of the hose? 20 A. Do you mean taking a swab out of -- of -- in 21 the hose itself, -- 22 Q. No. 23 A. -- is that what you're saying? 24 Q. I'm saying the only testing that Mr. 25 Albrecht did was collecting bacteria in an agar plate</p>
<p style="text-align: right;">Page 35</p> <p>1 MR. SACCHET: During the testing that Mr. 2 Albrecht discusses in his deposition transcript that 3 you relied on in opining that particles are at best an 4 indeterminate outcome of bacteria. 5 A. I'm opining that -- you're looking -- 6 If you're just looking at particles, that's 7 not looking at whether bacteria are on those 8 particles. 9 Q. And you have stated that -- 10 A. My understanding was what he was looking at 11 is whether or not there were particles. 12 Q. Okay. And you have stated that the 13 foundation for your testimony that particles are at 14 most an indeterminate outcome for bacteria is the 15 Albrecht testing; correct? 16 A. If -- if you're not looking -- if you're not 17 specifically looking at what those particles are, then 18 that's indirect evidence -- 19 Q. Are you -- 20 A. -- is what I'm -- what I'm saying. 21 Q. Okay. Are you -- 22 A. Is that -- 23 Q. Are you aware that Mr. Albrecht was only 24 testing whether bacteria could be cultured from the 25 air that came through the hose?</p>	<p style="text-align: right;">Page 37</p> <p>1 from air that came out of the hose of the device. 2 A. He was trying to do that, yes. 3 Q. And that's the only testing that he did. 4 A. No. He was doing other -- other testing. I 5 mean there was more to that ex -- those experiences he 6 was doing. He was trying a number of different 7 things. 8 Q. In terms of bacterial collection, did he do 9 anything else? 10 A. He also swabbed, I think, the -- the -- the 11 tube. 12 Q. Did he do anything else with respect to 13 either swabbing the interior of the tube or collecting 14 bacteria in an agar plate from the air that came 15 directly out of the hose? 16 A. I don't recall. I don't recall whether he 17 did or not. 18 Q. So you don't recall whether Mr. Albrecht did 19 any testing to see whether the Bair Hugger created 20 convection currents that caused bacteria in the 21 operating room to go to the surgical site. 22 A. I don't recall seeing any direct evidence 23 of -- of that. 24 Q. And you're aware that Dr. Samet has opined 25 that there are two mechanisms of infection; correct?</p>

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<p style="text-align: right;">Page 38</p> <p>1 A. Yes.</p> <p>2 Q. One mechanism is bacteria coming directly</p> <p>3 from the Bair Hugger device itself; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And the other mechanism is from the air --</p> <p>6 from the airflow being generated from the Bair</p> <p>7 Hugger --</p> <p>8 A. Yes.</p> <p>9 Q. -- causing bacteria to enter the surgical</p> <p>10 site; correct?</p> <p>11 A. Yes.</p> <p>12 Q. So you're not aware of whether Mr. Albrecht</p> <p>13 did any testing that goes to the second causal</p> <p>14 mechanism; correct?</p> <p>15 A. Well I mean I think the -- the mechanism</p> <p>16 we -- we've talked about where he's looking at the --</p> <p>17 at what came out -- came out of the -- out of the</p> <p>18 device, my assumption is that he was interested in</p> <p>19 that because that -- that would then en -- enter</p> <p>20 the -- the -- the air around the -- where -- where the</p> <p>21 surgery was being conducted, and that that would be a</p> <p>22 mode of -- for the -- for the second mode of -- of</p> <p>23 infection that Samet is talking about.</p> <p>24 Q. Dr. Samet does not conflate the first</p> <p>25 mechanism with the second mechanism; correct?</p>	<p style="text-align: right;">Page 40</p> <p>1 outcome of deep joint infections, it relates solely to</p> <p>2 the first causal mechanism that Dr. Samet described in</p> <p>3 his report.</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question, misstates the testimony.</p> <p>6 A. The -- the two mechanisms --</p> <p>7 I'm sorry, what -- what did you call the</p> <p>8 first one?</p> <p>9 Q. The first mechanism of infection is bacteria</p> <p>10 being blown directly out of the Bair Hugger onto the</p> <p>11 surgical site.</p> <p>12 A. Yes.</p> <p>13 Q. The second mechanism of infection that Dr.</p> <p>14 Samet describes is the Bair Hugger creating convection</p> <p>15 currents in the operating room airflow --</p> <p>16 A. Right. Okay.</p> <p>17 Q. -- that cause bacteria from anywhere in the</p> <p>18 operating room, not just the Bair Hugger device, --</p> <p>19 A. Right.</p> <p>20 Q. -- to enter the surgical field.</p> <p>21 A. Yes.</p> <p>22 Q. Mr. Albrecht's testing did not involve</p> <p>23 mechanism two.</p> <p>24 A. That's correct.</p> <p>25 Q. To the extent that you have opined that</p>
<p style="text-align: right;">Page 39</p> <p>1 A. Yes.</p> <p>2 Q. So there is an entirely separate mechanism</p> <p>3 which involves air being generated in the operating</p> <p>4 room --</p> <p>5 A. Yes.</p> <p>6 Q. -- that causes bacteria to land on the</p> <p>7 surgical site.</p> <p>8 A. Right.</p> <p>9 Q. Mr. Albrecht's test -- Mr. Albrecht's</p> <p>10 testing was about air coming out of the hose into an</p> <p>11 agar plate; correct?</p> <p>12 A. Yes.</p> <p>13 MR. GORDON: Objection, lack of foundation.</p> <p>14 Q. That does not directly involve whether</p> <p>15 airflow created currents that caused bacteria to enter</p> <p>16 the surgical site.</p> <p>17 A. It might, but it -- but -- but --</p> <p>18 Yeah. I mean it's not -- it's not directly</p> <p>19 testing it while the operation is -- is being</p> <p>20 conducted. He's -- he's trying to get indirect</p> <p>21 evidence of that -- that -- that -- that mechanism of</p> <p>22 where the infection could have been caused.</p> <p>23 Q. So to the extent that you have concluded</p> <p>24 based on Mr. Albrecht's testimony that particles are</p> <p>25 at most an indeterminate outcome -- intermediate</p>	<p style="text-align: right;">Page 41</p> <p>1 particles are at best an indeterminate outcome of deep</p> <p>2 joint infection, you are relying on Mr. Albrecht's</p> <p>3 testimony; correct?</p> <p>4 A. In part, yes.</p> <p>5 Q. You told me in full. Is there something</p> <p>6 else now that you're relying on to make that</p> <p>7 conclusion?</p> <p>8 A. Well the -- what he --</p> <p>9 As I understand it, what he was looking at</p> <p>10 was particles and without distinguishing exactly what</p> <p>11 those particles were, so what I'm saying, he looked --</p> <p>12 You know, there are particles there, that's</p> <p>13 part of what he shows; some of them may come directly</p> <p>14 from the hose, some of them maybe have been -- involve</p> <p>15 the second -- second mechanism where it disturbed the</p> <p>16 air around it and has particles from that. What I'm</p> <p>17 opining on is that the -- directly measuring bacteria</p> <p>18 or infectious agents on those particles, that's --</p> <p>19 that's what I was referring to.</p> <p>20 Q. But you would agree that Mr. Albrecht's</p> <p>21 testing did not directly relate to causal mechanism</p> <p>22 two. You've already said that.</p> <p>23 MR. GORDON: Object.</p> <p>24 A. Okay. Yes.</p> <p>25 Q. And so your conclusion, which are that</p>

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<p style="text-align: right;">Page 42</p> <p>1 particles are an indeterminate outcome of deep joint 2 infection, relies on Mr. Albrecht's conclusions as to 3 causal mechanism number one. 4 A. In -- in part, yes. But the -- 5 To say that what's on the particles, I mean 6 that -- that -- I'm -- I'm making that -- that -- that 7 claim generally. It's more than just looking at 8 whether or not the particles have been dispersed, it's 9 looking at what -- what's on those particles and 10 analyzing the content of those particles. 11 Q. Have you -- 12 A. And from what I can tell, there was no 13 analysis of the chemistry or direct measurements of 14 the -- of what if any organ -- any infectious 15 organisms were on those particles. 16 Q. So would it help you if there were studies 17 that linked particle concentration to bacterial 18 concentration? 19 MR. GORDON: Object to the form of the 20 question. 21 A. Are you -- you mean -- 22 Do you mean any studies or do you mean 23 studies particularly related to the Bair Hugger 24 device? 25 Q. I'm saying peer-reviewed literature that</p>	<p style="text-align: right;">Page 44</p> <p>1 A. It's a possibility. Again, it's -- it's -- 2 from when -- 3 When I say "indirect," the direct evidence 4 is ultimately the infection. That's the -- 5 Q. Okay. 6 A. That's the event you want to look at and 7 that's -- that's the event that's of most interest. 8 But the event you're talking about is whether or not 9 there's something on the particles. 10 Q. So if deep joint infection is the outcome of 11 interest, -- 12 A. Yes. 13 Q. -- it would be especially helpful if there 14 was an article that linked particles to bacteria, and 15 what I mean by that is that the more particles, the 16 more bacteria, but also found that the more bacteria, 17 the greater risk of infection. 18 A. Yes. 19 Q. That would be very helpful evidence in 20 determining whether the Bair Hugger increases the risk 21 of infection. 22 A. Well it's -- it's not directly related to 23 the Bair Hugger, but it would be -- yeah, it -- 24 it's -- it's helping to pose -- to understand what the 25 potential mechanism might be.</p>
<p style="text-align: right;">Page 43</p> <p>1 would conclude that particles are linked to bacteria. 2 MR. GORDON: Object to the form of the 3 question. 4 A. The parti -- I -- I -- 5 Yeah, I -- I don't under -- 6 Q. Okay. I'll rephrase. 7 Would it help if there was peer-reviewed 8 literature which concluded that as the number of 9 particles increase, so too do the number of bacteria? 10 MR. GORDON: Object to the form of the 11 question. 12 A. Always? 13 Q. In a randomized controlled trial in 14 orthopedic surgeries. 15 A. So you're analyzing the -- the particles 16 that are in the -- on the operating room during -- 17 during orthopedic surgery -- 18 Q. Yes. 19 A. -- and -- and looking at -- at -- 20 Yeah. If -- if there were -- if -- if I had 21 seen reports of that, I -- I would find that more 22 convincing, yes. 23 Q. And that would allow you to determine 24 whether an increase in particles could be linked to 25 bacteria.</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. What about studies that have -- that would 2 have concluded that the Bair -- Bair Hugger actually 3 increases the number of bacteria at the surgical site, 4 would that be helpful? 5 A. Yes. 6 Q. And studies that show that the Bair Hugger 7 increases the number of particles at the surgical 8 site. 9 A. Yes. Compared to, you know, whatever the 10 comparison group is, yes. 11 Q. Did you review any articles involving the 12 subject matter we just discussed, which is the 13 relationship of particles to bacteria and bacteria to 14 deep joint infection? 15 A. That was not really part of my -- my review, 16 no. 17 Q. So you have not reviewed the article by 18 Gregory Stocks; correct? 19 A. No. 20 Q. You have not reviewed the article by 21 Darouiche et al; correct? 22 A. Correct. 23 Q. You have not reviewed the article by 24 Moretti. 25 A. Correct.</p>

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<p style="text-align: right;">Page 46</p> <p>1 (Exhibit 7 was marked for 2 identification.) 3 BY MR. SACCHET: 4 Q. Doctor, this is an article authored by 5 Gregory Stocks; correct? 6 A. Yes. 7 Q. The title of the article is "Predicting 8 bacterial populations based on airborne particulates: 9 A study performed in nonlaminar flow operating rooms 10 during joint arthroplasty surgery;" correct? 11 A. That's the correct title, yes. 12 Q. The title involves the same subject matter 13 that we have just been discussing, which is the 14 relationship of particles to bacteria in orthopedic 15 surgeries; correct? 16 MR. GORDON: Object to the form of the 17 question, lack of foundation. 18 If you want him to read -- read it so he can 19 answer the question -- 20 MR. SACCHET: I asked if the title reflects 21 the subject matter that we have discussed. I said 22 nothing about the article itself. 23 A. It appears to, yes. 24 Q. And if I could turn your attention to the 25 bottom right-hand corner of the first page, do you see</p>	<p style="text-align: right;">Page 48</p> <p>1 A. "...nor surgery type..." that's what it 2 says. 3 Q. Yeah. And the second -- 4 And the next sentence says, "Surgery 5 duration, 5 micron to 9.99 micron particles per meter 6 cubed, greater than or equal to 10 micron particles 7 count per m cubed and staff count were each 8 significantly related (with a p-value of less than 9 .05) to the square root of the CFU per meters cubed;" 10 correct? 11 A. That's what it says, yes. 12 Q. Turning to the next page, in the right-hand 13 column, the first full paragraph begins with, "The 14 finding of a correlation..." Do you see that? 15 A. Yes. 16 Q. It states, "The finding of a correlation 17 between the number of 10 micron particles per meter -- 18 per m cubed and CFU per m cubed at the surgical site 19 has several important implications. First, it 20 supports airborne parti -- particulate contamination 21 of the wound as a source of postoperative infection in 22 joint arthroplasty, as emphasized by Edmiston et al." 23 Do you see that? 24 A. Yes. 25 Q. And finally on the last page, the last</p>
<p style="text-align: right;">Page 47</p> <p>1 the paragraph beginning, "The purpose of this study 2 was to determine whether the density of airborne 3 particulates at the surgery site and various behaviors 4 of operating room personnel can be used to predict the 5 density of viable airborne bacteria (ie, colony- 6 forming units (CFU) at the surgery site during hip and 7 knee joint arthroplasty?" 8 A. Yes. 9 Q. This -- 10 The purpose of this article was to determine 11 whether particulates are related to bacteria in 12 orthopedic surgery; correct? 13 A. Yes. 14 Q. If you could turn to the third page of the 15 study in the "RESULTS" section on the right-hand 16 column in the first full paragraph that begins "Table 17 2..." Do you see that? 18 A. Yes. 19 Q. The last sentence of that paragraph states, 20 "Neither sex nor surgery type was significantly 21 related to the square root CFU/m cubed;" correct? 22 I guess it's the second sentence. I 23 apologize. 24 A. Oh, oh, I -- okay. I was looking at the -- 25 Q. Do you see the third sentence?</p>	<p style="text-align: right;">Page 49</p> <p>1 paragraph of text, do you see where it starts, "We 2 have found..."? 3 A. Yes. 4 Q. And it relates that, "We have found that the 5 number of airborne particulates greater than 10 6 microns was correlated with the number of CFUs grown 7 from the air sampled within the sterile field 8 approximately 40 centimeters from surgical incision." 9 Do you see that? 10 A. Yes. 11 Q. Do you have any reason to doubt the 12 conclusions of Stocks et al? 13 A. I have not -- 14 This is the first I've -- first I've seen 15 this paper, so I would have to study it and -- to get 16 a better understanding of their methodology and what 17 they had done to -- to reach an opinion on this paper. 18 Q. Would it help you if one of 3M's past 19 experts had opined that the methods were good? 20 MR. GORDON: Object to the form of the 21 question. 22 A. No. 23 Q. Do you know Mr. Russ -- Mr. Russell 24 Olmstead, an epidemiologists and infectious -- 25 A. No, I don't know him.</p>

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<p style="text-align: right;">Page 50</p> <p>1 Q. -- disease doctor?</p> <p>2 A. No, I don't know him.</p> <p>3 Q. So you're not aware that he has stated that</p> <p>4 the methods of Stocks are well done.</p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question.</p> <p>7 A. I am not aware of what he -- what he has</p> <p>8 said about this paper. I'm not familiar with it.</p> <p>9 (Exhibit 8 was marked for</p> <p>10 identification.)</p> <p>11 BY MR. SACCHET:</p> <p>12 Q. The subject line of this e-mail is "Stocks</p> <p>13 Papers;" correct?</p> <p>14 A. Yes.</p> <p>15 Q. In the e-mail at the top we have a statement</p> <p>16 from Mr. Gary Hansen to a Mr. Russell Olmstead</p> <p>17 stating, "Could you send me a copy of the older Stocks</p> <p>18 paper? AJIC does not sell them on line." Do you see</p> <p>19 that?</p> <p>20 A. Yes.</p> <p>21 Q. And in the e-mail below that there are two</p> <p>22 paragraphs; correct?</p> <p>23 A. Yes.</p> <p>24 Q. And the text is from Russell Olmstead, do</p> <p>25 you see that?</p>	<p style="text-align: right;">Page 52</p> <p>1 A. I've --</p> <p>2 You just read me the paragraph, and I agree</p> <p>3 that you've read them correctly to me.</p> <p>4 Q. And as we established earlier, you said it</p> <p>5 would be helpful if there was peer-reviewed literature</p> <p>6 concluding that there was a link between particles and</p> <p>7 bacteria; correct?</p> <p>8 A. Well it would be helpful if I -- if it</p> <p>9 was not only peer-reviewed but I had a chance to</p> <p>10 review it.</p> <p>11 Q. So --</p> <p>12 A. I'm not going to take a peer-reviewed</p> <p>13 article --</p> <p>14 You know, every peer-reviewed article is</p> <p>15 not -- is not -- not appro -- not correct, --</p> <p>16 Q. Okay.</p> <p>17 A. -- so I need --</p> <p>18 One needs a chance to actually review the</p> <p>19 science and digest what -- what was -- the work that</p> <p>20 was actually done to reach a conclusion.</p> <p>21 Q. So you did not review this article in</p> <p>22 opining that particles are at most an indeterminate</p> <p>23 outcome of deep joint infection.</p> <p>24 A. That's correct.</p> <p>25 Q. You also said that it would be helpful if</p>
<p style="text-align: right;">Page 51</p> <p>1 A. Yes.</p> <p>2 Q. And the first line says, "Hi Gary: fairly</p> <p>3 remarkable paper given an ability to present during</p> <p>4 actual procedures. I had not seen it so thanks for</p> <p>5 bringing it to my attention. Demonstrates that pre</p> <p>6 press page is useful place to visit often. It is</p> <p>7 difficult to get IRB approval for such investigations.</p> <p>8 I don't know the authors but the methods employed are</p> <p>9 very good and I like the use of electronic particle</p> <p>10 counts AND bacterial air sampling. Very helpful</p> <p>11 picture of what happens in a typical non-</p> <p>12 unidirectional HVAC design." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Do you have any reason to doubt that the</p> <p>15 methods in this paper are anything but well designed?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, also lack of foundation.</p> <p>18 A. I don't un -- I mean I -- I -- that's --</p> <p>19 That's this person's review of it, that's</p> <p>20 his opinion of it. I agree -- I agree that that's his</p> <p>21 opinion. I don't have an opinion on it because I have</p> <p>22 not reviewed it.</p> <p>23 Q. But you have seen that this article has</p> <p>24 concluded that there is a link between airborne</p> <p>25 particulates and bacteria; correct?</p>	<p style="text-align: right;">Page 53</p> <p>1 there were articles that concluded that particles were</p> <p>2 not only related to bacteria but also that bacteria</p> <p>3 was related to deep joint infection; correct? That's</p> <p>4 what you testified to.</p> <p>5 A. Yes.</p> <p>6 Q. Have you reviewed any such articles,</p> <p>7 professor?</p> <p>8 A. No, I haven't. I mean it's -- it's -- this</p> <p>9 is not --</p> <p>10 That particular part of it is not really my</p> <p>11 area.</p> <p>12 Q. So it's not your area, but you concluded</p> <p>13 that particles are at most an indeterminate outcome of</p> <p>14 infection.</p> <p>15 A. I --</p> <p>16 The infection is the ultimate outcome that I</p> <p>17 was interested in in looking at the McGovern paper, so</p> <p>18 it's the occurrence of the infection which is -- which</p> <p>19 is the outcome that I was most interested in. Whether</p> <p>20 there's infectious organisms on particles is basically</p> <p>21 an intermediate step which would be helpful of</p> <p>22 understanding, perhaps, how they got there.</p> <p>23 Q. Okay.</p> <p>24 A. But it's not the outcome that I was</p> <p>25 particularly interested in.</p>

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<p style="text-align: right;">Page 54</p> <p>1 Q. So let's look at this paper which --</p> <p>2 THE REPORTER: Just a moment.</p> <p>3 (Exhibit 9 was marked for</p> <p>4 identification.)</p> <p>5 BY MR. SACCHET:</p> <p>6 Q. The title of this article is the</p> <p>7 "Association of Airborne Microorganisms in the</p> <p>8 Operating Room With Implant Infections: A Randomized</p> <p>9 Controlled Trial;" correct?</p> <p>10 A. Yes.</p> <p>11 Q. The title of this article relates to the</p> <p>12 relationship of airborne microorganisms to infection;</p> <p>13 correct?</p> <p>14 A. That's what the title is, yes.</p> <p>15 Q. That is the subject matter by which you</p> <p>16 testified one minute ago that it would be helpful to</p> <p>17 review to determine whether bacteria are related to</p> <p>18 the outcome of interest, deep joint infection;</p> <p>19 correct?</p> <p>20 A. That would be helpful for under -- to</p> <p>21 perhaps get an understanding of the mechanisms, yes.</p> <p>22 Q. The objective of the paper was to, quote,</p> <p>23 "To evaluate the association of airborne colony-</p> <p>24 forming units (CFU) at incision sites during</p> <p>25 implantation of prostheses with the incidence of</p>	<p style="text-align: right;">Page 56</p> <p>1 related to total particulate density (with a p-value</p> <p>2 of less than .001) in the control group, indicating</p> <p>3 that airborne particle counts may be used as a proxy</p> <p>4 for ambient CFU density." Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. On page eight of this study, very last</p> <p>7 paragraph, do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. "In conclusion, our results indicate that</p> <p>10 CFU contamination of air at the incision site is a</p> <p>11 risk factor for implant but not incisional infections.</p> <p>12 CFU contamination is related to the particulate</p> <p>13 density in the air at the incision site, and both CFU</p> <p>14 and particulate density are a function of the number</p> <p>15 of people in the operating room. Limiting airborne</p> <p>16 CFU contamination at the incision site can be expected</p> <p>17 to lower implant infection risk."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. You have no reason to doubt that conclusion;</p> <p>21 do you?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, lack of foundation.</p> <p>24 A. That conclusion would be based on the -- the</p> <p>25 whole study, and you've just given me this study, and</p>
<p style="text-align: right;">Page 55</p> <p>1 either incisional or prosthesis-related surgical site</p> <p>2 infections;" correct?</p> <p>3 A. Yes.</p> <p>4 Q. This was a randomized controlled trial;</p> <p>5 correct?</p> <p>6 A. That's what it says.</p> <p>7 Q. Randomized controlled trials are first-tier</p> <p>8 scientific evidence; correct?</p> <p>9 A. They can be, yes.</p> <p>10 Q. Are there other types of studies that are</p> <p>11 given more weight than RCTs?</p> <p>12 A. In general, they're -- they're given the</p> <p>13 most weight, yes, if they're well done.</p> <p>14 Q. If we could turn to page six, and you'll see</p> <p>15 the pages are listed on the top of the paper, under</p> <p>16 the header "CFU and Particulate Densities and</p> <p>17 Infection," do you see that heading?</p> <p>18 A. Yes.</p> <p>19 Q. It states, "CFU density at incision sites</p> <p>20 was significantly related to incidence of implant</p> <p>21 infections (with a p-value of .021), but not of</p> <p>22 incisional infections (with a p-value of .687). Every</p> <p>23 10 CFU per m cubed increase in median CFU denies</p> <p>24 approximately doubled the probability of implant</p> <p>25 infection (Figure 4). CFU density was positively</p>	<p style="text-align: right;">Page 57</p> <p>1 I haven't had a chance to really study this paper, so</p> <p>2 I would -- I would need to study the paper in order</p> <p>3 to -- to have an opinion on that conclusion.</p> <p>4 Q. You didn't study the paper, but you did</p> <p>5 conclude that particles are at best an indeterminate</p> <p>6 outcome of infection; correct?</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question.</p> <p>9 A. I -- I concluded, as I've -- I've explained</p> <p>10 the reason my --</p> <p>11 What I meant when I said that is that that</p> <p>12 was a diff -- an intermediate outcome. I mean what</p> <p>13 you have read to me does not --</p> <p>14 I didn't see that the Bair Hugger was</p> <p>15 involved with this. Is that correct?</p> <p>16 Q. The Bair Hugger was not involved in this</p> <p>17 study.</p> <p>18 A. Okay.</p> <p>19 Q. Would it help you if I showed you studies --</p> <p>20 A. If you --</p> <p>21 If this study had used the Bair Hugger, that</p> <p>22 would help.</p> <p>23 Q. Would it help you if I showed you studies</p> <p>24 showing the Bair Hugger increasing particles or</p> <p>25 increasing bacteria?</p>

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<p style="text-align: right;">Page 58</p> <p>1 MR. GORDON: Object to the form of the 2 question, compound. 3 A. Well which -- which -- 4 What is the outcome that you're -- you're 5 showing me? 6 Q. So we have a study here, and you would agree 7 that it has concluded that particles have a 8 relationship to bacteria and bacteria has a 9 relationship to deep joint infection; correct? 10 MR. GORDON: Are you talking about Exhibit 11 8? 12 MR. SACCHET: I'm talking about Exhibit -- 13 A. Exhibit 9? 14 MR. SACCHET: -- 9. 15 A. What? 16 Q. This paper concludes -- 17 A. This one is 9. 18 Q. Darouiche, Exhibit 9. 19 A. Yeah, okay. 20 Q. -- that the amount of particles is related 21 to the amount of bacteria; correct? 22 A. That's what they -- that's this paper -- 23 that's -- 24 That's what they found in -- in this trial. 25 Q. Yes.</p>	<p style="text-align: right;">Page 60</p> <p>1 MR. GORDON: Object to the form of the 2 question, lack of foundation, incomplete hypothetical. 3 Q. It's a simple syllogism: Premise one, 4 particles relate to bacteria; premise two, bacteria 5 relates to deep joint infection. Q.E.D., if Bair 6 Hugger increases particles, does it increase bacteria? 7 MR. GORDON: Object to the form of the 8 question, lack of foundation, it's an incomplete 9 hypothetical. 10 A. You haven't -- you -- you haven't shown the 11 whole -- whole scenario. 12 Q. What's the whole scenario? 13 A. Well that -- that you used the Bair -- used 14 the Bair Hugger -- 15 Q. Yeah. 16 A. -- and that in turn increases your risk 17 of -- the risk of infection. 18 Q. So you would only conclude that the Bair 19 Hugger increases infection if there was a study 20 showing the Bair Hugger increases the risk of 21 infection. 22 MR. GORDON: Object to the form of the 23 question. 24 A. I would -- I would want to see a well- 25 controlled study that showed that use of the Bair</p>
<p style="text-align: right;">Page 59</p> <p>1 A. That appears to be from the limited reading 2 that -- that we've just done. 3 Q. You have seen that it's a randomized 4 controlled trial. 5 A. I've seen it described there. I have not 6 reviewed exactly what they did, how they did the 7 randomization. 8 Q. And this paper also concludes that the 9 number of bacteria increase -- as the bacteria 10 increases, that increases the risk of DJI, deep joint 11 infection; correct? 12 A. That is their -- that is their conclusion, 13 yes. 14 Q. If this paper did not involve the Bair 15 Hugger, would it help you to see studies that conclude 16 that the Bair Hugger increases particles? 17 A. It would -- it would help to see that it 18 increases particles and it increases the -- the risk 19 of infection. 20 Q. If this paper establishes a link between 21 particles, bacteria and infection, -- 22 A. Yes. 23 Q. -- and the Bair Hugger increases particles, 24 is it your testimony that one cannot also conclude 25 that the Bair Hugger increases bacteria?</p>	<p style="text-align: right;">Page 61</p> <p>1 Hugger during surgery increased risk of -- of -- of 2 infection. 3 Q. Epidemiology considers more than evidence 4 that draws a unidirectional link between a variable 5 and an outcome; correct? 6 MR. GORDON: Object to the form of the 7 question. 8 A. Yeah. I don't understand the question. 9 Q. Part of epidemiology considers the mechanism 10 of infection; correct? 11 A. That's one aspect of interest, yes. 12 Q. That relates to the coherency of whether a 13 cause increases an outcome; correct? 14 A. That's one of the considerations, is the 15 mech -- is -- is the mechanism. 16 Q. And when you consider a mechanism, you can 17 consider intermediate outcomes that lend biological 18 plausibility to causal inference; correct? 19 A. Well intermediate outcomes very often 20 have -- have -- have not worked out in ep -- in 21 epidemiological studies. Sometimes -- sometimes -- 22 Q. I'm going to -- I'm going to interrupt you 23 and mover to strike. The question is -- 24 MR. GORDON: No. Let him answer the 25 question, then you can move to strike if you don't</p>

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<p style="text-align: right;">Page 62</p> <p>1 like it, but don't cut -- don't cut him off during 2 the -- his answer. 3 A. I mean there -- there are many -- there are 4 many studies that look at intermediate outcomes 5 that -- 6 Q. Okay. 7 A. -- that you find an association with 8 intermediate outcomes, but then the main one of 9 interest, which is the primary -- primary point, is -- 10 is not in fact demonstrated. And it -- and it could 11 be due to a number of things; it may be that you have 12 the wrong idea of what the actual mechanism is. 13 Q. In your view, what is the dose at issue in 14 this litigation? 15 MR. GORDON: Object to the form of the 16 question, lack of foundation. 17 A. Dose. 18 Q. Dose is one of the criteria for determining 19 causal inference; correct? 20 A. One of the things that's often of interest 21 is -- is not a -- a particular dose. 22 What dose do you have in mind? I didn't -- 23 Q. As something increases, an outcome could 24 increase. 25 A. Okay. That -- so that would be a</p>	<p style="text-align: right;">Page 64</p> <p>1 MR. SACCHET: We've just reviewed a study on 2 the topic, so there is foundation. 3 A. But -- 4 MR. GORDON: I mean -- 5 A. -- there's no evidence of what the dose -- 6 the dose of bacteria is that's coming from that -- 7 from the Bair Hugger. 8 Q. If the Bair Hugger increases the amount of 9 bacteria -- 10 A. But you're not measuring the dose. 11 Q. If it is found that the Bair Hugger 12 increases the amount of bacteria -- 13 A. Well the dose/response relationship is that 14 you measure different doses and that affects your 15 risk. 16 Q. Would it help you if there were -- 17 A. No one has measured the dose -- the dose of 18 bacteria that's come -- that's come from the Bair 19 Hugger. 20 Q. Do you know that a single bacterium can 21 cause a deep joint infection? 22 A. Yes. 23 Q. So does dose matter if the more bacteria you 24 have and that one bacteria can cause an infection? 25 MR. GORDON: Object to form. Object to the</p>
<p style="text-align: right;">Page 63</p> <p>1 dose/response relationship. A dose/response 2 relationship would be -- would be one important thing 3 to look at. 4 Q. What -- 5 In your view what is -- what is the material 6 dose with respect to whether the Bair Hugger increases 7 infection? 8 MR. GORDON: Object to the form of the 9 question, lack of foundation. 10 A. I don't -- I don't recall seeing in any of 11 the -- the -- the -- for example, the McGovern study, 12 anything on dose of Bair Hugger. You either use it or 13 you don't. It's a binary -- 14 Q. What causes infection? 15 MR. GORDON: Object -- same objections. 16 A. What causes -- 17 Q. What -- what -- what thing leads to an 18 infection? Particles? Bacteria? What? 19 MR. GORDON: Object. 20 A. Bacteria. 21 Q. So is bacteria the dose, because the more 22 bacteria you have, the greater incidence of deep joint 23 infection? 24 MR. GORDON: Object to the form of the 25 question, lack of foundation.</p>	<p style="text-align: right;">Page 65</p> <p>1 form of the question, lack of foundation. 2 Q. If -- if one bacteria can cause an infection 3 and the more bacteria that you have increases the risk 4 of infection, it stands to reason that the 5 dose/response relationship as to how much the Bair 6 Hugger might produce in -- in terms of bacteria is not 7 the relevant question. 8 MR. GORDON: Object to form, also -- also 9 lack of foundation. 10 A. I mean you're -- you're not -- 11 There's no data that you're showing me 12 that -- that relates -- that I have seen -- 13 Q. Yeah. 14 A. -- related to the Bair Hugger -- 15 Q. Okay. 16 A. -- that indicates the dose of bacteria that 17 each of these patients was exposed to. 18 Q. Would a study showing that the Bair Hugger 19 increases the amount of bacteria at the surgical site 20 help you? 21 A. You -- you -- 22 To establish a dose/response relationship, 23 you need to know what the dose is. 24 Q. So the only way that you would draw any 25 inference about whether the number of bacteria from</p>

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<p style="text-align: right;">Page 66</p> <p>1 the Bair Hugger increases the risk of infection is if 2 you knew the dose/response relationship? 3 MR. GORDON: Object to the form of the 4 question. 5 A. You're the one that raised the issue of 6 there being a dose/response relationship. 7 Q. And my question is: What is the dose at 8 issue? Bacteria? 9 A. I guess -- 10 Well I don't know. You're the one that 11 raised it. I haven't -- I've -- as I've -- as I've 12 said, I have not seen anything in these studies that 13 measures dose. It could be the num -- the level of 14 bacteria, it could be how long you were in surgery, it 15 could be, you know, how -- I don't know if there's 16 different settings of these -- of these -- on -- on 17 the Bair Hugger, but I mean there are -- or -- or for 18 that matter any heating -- warming device, so it's -- 19 Those would be some measurements of -- of 20 dose. 21 Q. Okay. 22 A. And these studies did not do that. 23 Q. Okay. 24 MR. SACCHET: We're going to pass you what 25 will be marked as Exhibit 10.</p>	<p style="text-align: right;">Page 68</p> <p>1 MR. GORDON: Counsel, is there -- 2 Where is page seven through 113? 3 MR. SACCHET: They are not included. 4 MR. GORDON: Well I'm going to object to 5 this document on the grounds of completeness. 6 MR. SACCHET: That's fine. 7 Q. Page 114 is entitled "Workgroup 4;" correct? 8 A. Yes. 9 Q. On the operating room -- "Operative 10 Environment;" correct? 11 A. Yes. 12 Q. And beneath that we see numerous 13 delegates -- delegates, all of whom have M.D.s; 14 correct? 15 A. They seem to, yes. 16 Q. Okay. On page 115, question one states, "Do 17 numbers of bacteria arriving in the surgical wound 18 correlate directly with probability of SSI?" Do you 19 see that? 20 A. Yes. 21 Q. And the consensus statement reads, "We 22 recognize that the probability of surgical site 23 infection correlates directly with the quantity of 24 bacteria that reach the wound. Accordingly we support 25 strategies to lower particulate and bacterial counts</p>
<p style="text-align: right;">Page 67</p> <p>1 (Exhibit 10 was marked for 2 identification.) 3 BY MR. SACCHET: 4 Q. Have you seen this document before, 5 Professor Holford? 6 A. No, I have not. 7 Q. The title of the document is the 8 "Proceedings of the International Consensus Meeting on 9 Periprosthetic Joint Infection;" correct? 10 A. Yes. 11 Q. Do you know who Javad Parvizi is? 12 A. No, I do not. 13 Q. So you don't know that he is a consultant 14 for 3M? 15 A. No, I don't. 16 Q. Okay. If you turn to page six, do you see 17 the 3M logo? 18 A. Yes. 19 Q. And above that we see the text "Platinum 20 Sponsor;" correct? 21 A. Yes. 22 Q. So 3M was a platinum sponsor of this 23 consensus; correct? 24 A. Apparently. 25 Q. The next page is page 114.</p>	<p style="text-align: right;">Page 69</p> <p>1 at surgical wounds. 2 "Delegate Vote: Agree: 97 percent, (Strong 3 consensus)." 4 Do you see that, professor? 5 A. Yes, I do. 6 Q. Do you have any reason to doubt the 7 consensus statement of these medical doctors? 8 MR. GORDON: Object to the form of the 9 question. 10 A. I -- I mean that's their opinion. That's -- 11 Yes. 12 Q. And this opinion states that the number of 13 bacteria at the surgical site relates to the incidence 14 of surgical-site infection; correct? 15 A. Yes. 16 Q. Okay. Does that explain that the number of 17 bacteria could be viewed as the dose at issue with 18 respect to surgical-site infection? 19 MR. GORDON: Object to the form of the 20 question, also lack of foundation. 21 A. The -- the -- the problem I -- I -- 22 I mean I'm not sure what connection you're 23 looking at. As the statement is -- 24 Q. Okay. 25 A. -- as -- if the --</p>

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<p style="text-align: right;">Page 70</p> <p>1 If you have different levels of -- of</p> <p>2 bacteria at the surgical site, you will affect the</p> <p>3 risk.</p> <p>4 Q. Uh-huh. And the more bacteria at the</p> <p>5 surgical site, the increased risk of infection.</p> <p>6 A. That's -- that's what they're -- they're</p> <p>7 concluding, yes.</p> <p>8 Q. Okay. And question two says, "Do numbers of</p> <p>9 bacteria in the operating room environment correlate</p> <p>10 directly with the probability of surgical site</p> <p>11 infection?" And the consensus on that states, "We</p> <p>12 recognize that airborne particulate bacteria are a</p> <p>13 major source of contamination in the operating room</p> <p>14 environment and that bacteria shed by personnel are</p> <p>15 the predominant source of these particles. The focus</p> <p>16 of our recommendation is to reduce the volume of</p> <p>17 bacteria in the operating room with particular</p> <p>18 attention to airborne particles."</p> <p>19 A. Okay.</p> <p>20 Q. This consensus draws a relationship between</p> <p>21 bacteria and particles; correct?</p> <p>22 A. Yes.</p> <p>23 Q. And 93 percent of the delegates agreed to</p> <p>24 that link.</p> <p>25 A. Well they're --</p>	<p style="text-align: right;">Page 72</p> <p>1 A. The third --</p> <p>2 Q. The third sentence. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. "Bacteria can be considered as part of the</p> <p>5 total mass of particulates in the air. Some studies</p> <p>6 have suggested that the airborne parti -- particulate</p> <p>7 count should be considered as a potential surrogate</p> <p>8 for airborne microbial density. Others have found</p> <p>9 correlation between the number of particles larger</p> <p>10 than 10 micrometers with a density of viable bacteria</p> <p>11 at the surgery measured by colony-forming units." Do</p> <p>12 you see that?</p> <p>13 A. Yes.</p> <p>14 Q. So the justification for the consensus</p> <p>15 statement involves the relationship between particles</p> <p>16 and bacteria.</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, lack of foundation.</p> <p>19 A. I mean there again, the --</p> <p>20 I don't think the intent of the statement is</p> <p>21 any old particle. They're interested in particles</p> <p>22 that have bacteria on them.</p> <p>23 Q. I'll read the sentence again.</p> <p>24 A. Well that's what this sentence is, but I</p> <p>25 mean this is what the question is.</p>
<p style="text-align: right;">Page 71</p> <p>1 It's not just particles, they're talking</p> <p>2 about bacteria. Right?</p> <p>3 Q. The relationship of part --</p> <p>4 A. Do the -- do the number of bacteria in the</p> <p>5 operating room correlate directly with the probability</p> <p>6 of surgical-site infection, so it's -- you --</p> <p>7 I think you stated the question as</p> <p>8 "particles."</p> <p>9 Q. And it says there should be particular</p> <p>10 attention to airborne particles; correct?</p> <p>11 A. Where are you reading?</p> <p>12 Q. From the consensus statement at the top of</p> <p>13 page 116.</p> <p>14 A. It's referring again to the bacterial</p> <p>15 particles.</p> <p>16 Q. And it says, "The focus of our</p> <p>17 recommendation is to reduce the volume of bacteria in</p> <p>18 the operating room with particular attention to</p> <p>19 airborne particles;" correct?</p> <p>20 A. Well, but the particles that they're</p> <p>21 referring to are airborne particulate bacteria.</p> <p>22 Q. Okay. Let's look at the justification,</p> <p>23 which is the paragraph below that. The third</p> <p>24 statement begins with "Bacteria can be considered..."</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. The justification for the answer draws a</p> <p>2 link between airborne particles and bacteria; correct?</p> <p>3 A. There --</p> <p>4 Yes, they are saying there is a</p> <p>5 relationship.</p> <p>6 Q. And you have --</p> <p>7 A. There often is a relationship.</p> <p>8 Q. Okay.</p> <p>9 A. That's what they're saying.</p> <p>10 Q. You have no reason to doubt that</p> <p>11 relationship; correct?</p> <p>12 A. But the --</p> <p>13 It depends on what the -- what the</p> <p>14 conditions are in that particular operating room.</p> <p>15 Q. You have no expertise in airborne particles</p> <p>16 is your testimony from earlier this morning.</p> <p>17 A. Okay. So I mean --</p> <p>18 So I don't understand your question.</p> <p>19 Q. So --</p> <p>20 A. If you're saying I don't --</p> <p>21 Q. You have a reason to doubt the conclusion</p> <p>22 even though you don't have expertise in the subject</p> <p>23 matter is my point.</p> <p>24 A. I'm not --</p> <p>25 MR. GORDON: Object to the form of the</p>

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<p style="text-align: right;">Page 74</p> <p>1 question.</p> <p>2 A. I'm not -- I'm -- I'm not dis -- disputing</p> <p>3 what I think they are saying, --</p> <p>4 Q. Okay.</p> <p>5 A. -- which is that -- relates, again, to the</p> <p>6 particles and what is -- what those particles are.</p> <p>7 Q. So when they say there is a correlation</p> <p>8 between the number of particulates with a density of</p> <p>9 viable bacteria, you're interpreting that statement to</p> <p>10 mean that those particles already are bacteria?</p> <p>11 A. If you're in an environment that is somehow</p> <p>12 spraying out part -- particles that are sterile, are</p> <p>13 you -- are you going to use this -- are you using</p> <p>14 this -- their statement here that you're increase --</p> <p>15 you are at increased risk of infection? Is that what</p> <p>16 you're arguing?</p> <p>17 Q. If there is a correlation between the number</p> <p>18 of particles and bacteria is what it says.</p> <p>19 A. From the circumstances that I've described,</p> <p>20 there's not going to be a correlation.</p> <p>21 Q. That may be very well in some circumstances,</p> <p>22 but --</p> <p>23 A. Exactly.</p> <p>24 Q. -- it varies in other circumstances</p> <p>25 according to the consensus statement.</p>	<p style="text-align: right;">Page 76</p> <p>1 A. There have been some studies, yes.</p> <p>2 Q. And some can include all as a logical</p> <p>3 matter; correct?</p> <p>4 A. Some can --</p> <p>5 Q. Some can be all.</p> <p>6 A. All studies have found this?</p> <p>7 Q. I'm just saying it's -- there's --</p> <p>8 There's no point in arguing over the</p> <p>9 semantics, but have you read 3M's -- the deposition of</p> <p>10 3M's corporate representative in this litigation?</p> <p>11 A. No, I have not.</p> <p>12 Q. You have not. So you're not aware that the</p> <p>13 corporate representative for 3M testified that every</p> <p>14 single study indicates that the Bair Hugger increases</p> <p>15 the particle count over the surgical field?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence, lack of</p> <p>18 foundation.</p> <p>19 A. I -- I have not seen that. I hadn't -- had</p> <p>20 not seen that -- that testimony, so I --</p> <p>21 I had not seen that statement.</p> <p>22 MR. GORDON: Are we reaching a point where</p> <p>23 we can take a quick break?</p> <p>24 MR. SACCHET: In a little bit, yeah. I'll</p> <p>25 try to move through this.</p>
<p style="text-align: right;">Page 75</p> <p>1 A. There are --</p> <p>2 Exactly.</p> <p>3 Q. So you would agree in some circumstances --</p> <p>4 A. In some circumstances, yes.</p> <p>5 Q. -- there is a relationship between particle</p> <p>6 load and bacterial load.</p> <p>7 A. In some circumstances.</p> <p>8 Q. And in some circumstances the relationship</p> <p>9 between bacterial load also relates to the increased</p> <p>10 risk of infection; correct?</p> <p>11 A. Yes.</p> <p>12 Q. Are you aware that the Bair Hugger increases</p> <p>13 particles in the operating room?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. I'm -- I'm aware that -- that some of</p> <p>17 the -- some of the studies seem to suggest that</p> <p>18 there -- that there is a -- an increase.</p> <p>19 Q. I notice that you used the word "some" in</p> <p>20 your report as well. That's true; correct?</p> <p>21 A. I don't recall what I -- exactly what I --</p> <p>22 my wording was.</p> <p>23 Q. But your testimony today is that some</p> <p>24 studies show an increase in particulate load over the</p> <p>25 surgical site.</p>	<p style="text-align: right;">Page 77</p> <p>1 (Exhibit 11 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. This on the cover page has been denoted as</p> <p>5 the deposition of Albert Van Duren. Do you see that,</p> <p>6 Dr. Holford?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And turning to the back side of the</p> <p>9 paper, there are lines of testimony; correct? Do you</p> <p>10 see page 258 internal?</p> <p>11 A. Yes.</p> <p>12 Q. Do you see lines five through 10?</p> <p>13 A. Yes.</p> <p>14 Q. Line five states: "Based on the data that</p> <p>15 we have today, including the study funded by 3M as</p> <p>16 well as other studies, every single study indicates</p> <p>17 that the Bair Hugger increases the particle count over</p> <p>18 the sterile field; correct?"</p> <p>19 "Answer: In absolute numbers, yes.</p> <p>20 "Question: Okay. And you have no internal</p> <p>21 study to refute that; correct?</p> <p>22 "No, we don't."</p> <p>23 A. Okay.</p> <p>24 Q. Does this clarify your position as to</p> <p>25 whether some studies have shown an increase in</p>

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<p style="text-align: right;">Page 78</p> <p>1 particles over the surgical site as a result of the 2 Bair Hugger?</p> <p>3 MR. GORDON: Object to the form of the 4 question, lack of foundation.</p> <p>5 A. There are some -- there are some studies.</p> <p>6 Q. Does this --</p> <p>7 A. I don't think --</p> <p>8 Q. -- testimony from 3M use the word "all" or 9 "some?"</p> <p>10 MR. GORDON: Object to the form of the 11 question, lacks foundation.</p> <p>12 A. I mean I've -- I've -- what -- what you're 13 showing me is just this one -- one statement. I don't 14 know what all went before this. My impression from 15 what you just read is that when they say "all," 16 there's a whole set of studies that came before this 17 and the "all" of refers to those.</p> <p>18 Q. Do you know any studies that have not found 19 an increase in particles over the surgical site after 20 use of the Bair Hugger?</p> <p>21 A. No, I don't.</p> <p>22 Q. You reviewed the McGovern study; correct?</p> <p>23 A. Yes. I don't recall that the -- I don't 24 recall the -- the McGovern study actually measuring 25 particles over the surgical -- over the surgical site.</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. You're not aware that the Belani study found 2 that there was an increase in bubbles over the 3 surgical site after the use of the Bair Hugger 4 compared to a conductive warming device.</p> <p>5 A. I'm not familiar with that, no.</p> <p>6 Q. Have you reviewed the Sessler study?</p> <p>7 A. No, I have not.</p> <p>8 Q. You're not aware that the Sessler study also 9 found an increase in particles over the surgical site 10 from the use of the Bair Hugger when it was on versus 11 when it was off.</p> <p>12 MR. GORDON: Object to the form of the 13 question, assumes facts not in evidence, misstates the 14 testimony.</p> <p>15 A. I'm not familiar with the -- with the -- 16 with the findings of that study, no.</p> <p>17 Q. Have you reviewed any studies that show that 18 the Bair Hugger increases the amount of bacteria over 19 the surgical site?</p> <p>20 A. No, I'm not familiar with that.</p> <p>21 MR. SACCHET: Just maybe five more minutes. 22 (Exhibit 12 was marked for 23 identification.)</p> <p>24 BY MR. SACCHET: 25 Q. The title of this article, professor, is</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. Is a bubble a particle?</p> <p>2 A. The bubble part of it was not taking place 3 during -- during surgery.</p> <p>4 Q. It was a simulated surgery; correct?</p> <p>5 A. It was simulated.</p> <p>6 Q. Right.</p> <p>7 A. It was not the actual surgery.</p> <p>8 Q. Fair enough. But they did find an increase 9 of bubbles over the surgical site from the use of the 10 Bair Hugger compared to a conductive warming device.</p> <p>11 A. Yes. I read that part of it, yes.</p> <p>12 Q. You reviewed the Legg studies; correct?</p> <p>13 A. No, I don't think I did.</p> <p>14 Q. You didn't. So you're not aware that the 15 2013 Legg study found a one-thousand-times increase in 16 particles over the surgical site from the use of the 17 Bair Hugger compared to a radiant warming device.</p> <p>18 A. I'm not familiar with that study, no.</p> <p>19 Q. You're not aware that the 2012 Legg study 20 also found a statistically significant increase in 21 particles over the surgical site after use of the Bair 22 Hugger device.</p> <p>23 A. I am not familiar with that one.</p> <p>24 Q. Have you reviewed the Belani study?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 81</p> <p>1 "Convection warmers -- a possible source of 2 contamination in laminar airflow operating theatres?" 3 Correct?</p> <p>4 A. Yes.</p> <p>5 Q. Do you see in the summary in the second line 6 from the bottom, it starts, "This study" -- or I 7 apologize. "A further small rise..." Do you see the 8 beginning of that sentence, third-to-the-last 9 statement in the abstract?</p> <p>10 A. Yes.</p> <p>11 Q. "A small -- A further small rise is seen 12 after the convection heaters were turned on when 13 applied to patients. This study showed that use of 14 warm air convection heaters on patients produced a 15 small increase in the number of colony forming units 16 in ultra-clean air theatres but the levels were 17 unlikely to have clinical significance." Do you see 18 that?</p> <p>19 A. Yes.</p> <p>20 Q. So this study, based on the summary -- and I 21 understand you have not reviewed it in whole -- does 22 conclude that there was as small increase in bacteria 23 from a convection warmer.</p> <p>24 MR. GORDON: Object to the form of the 25 question, --</p>

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<p style="text-align: right;">Page 82</p> <p>1 A. That was --</p> <p>2 MR. GORDON: -- lack of foundation.</p> <p>3 A. That was unlikely to have clinical</p> <p>4 significance.</p> <p>5 Q. Okay. And would it help if there were a</p> <p>6 study that showed that there was a statistically</p> <p>7 significant difference in terms of the amount of</p> <p>8 bacteria produced by the Bair Hugger when it was on</p> <p>9 versus off?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question, lack of foundation, incomplete hypothetical.</p> <p>12 A. Well I mean statistical significance is</p> <p>13 not -- well it's -- it's part of what -- what would be</p> <p>14 convincing, but it also has to do with the magnitude</p> <p>15 of what that effect would be, of whether or not it</p> <p>16 would have a clinical -- you know, be clinically</p> <p>17 important.</p> <p>18 Q. Statistical significance is not the same as</p> <p>19 clinical significance; correct?</p> <p>20 A. Correct.</p> <p>21 Q. And epidemiology does not hinge on whether a</p> <p>22 result is statistically significant or not; correct?</p> <p>23 A. Well the -- the -- for --</p> <p>24 To definitely demonstrate a -- an</p> <p>25 epidemiological effect, you'd want the association to</p>	<p style="text-align: right;">Page 84</p> <p>1 question to whether you're interested in it.</p> <p>2 Whether something is statistically</p> <p>3 significant or not is a different question than</p> <p>4 whether it's clinically significant.</p> <p>5 A. It is a different question.</p> <p>6 Q. Okay.</p> <p>7 A. Yes.</p> <p>8 Q. Statistical significance is not equivalent</p> <p>9 to scientific, human, or economic significance;</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. One of the reasons why you say the McGovern</p> <p>13 study has no import with respect to the relationship</p> <p>14 between the Bair Hugger and deep joint infection is</p> <p>15 that, based on using Fisher's exact test instead of</p> <p>16 chi-squared and based on Albrecht's Exhibit 10, the</p> <p>17 p-value is .0507; correct?</p> <p>18 MR. GORDON: Object to the form of the</p> <p>19 question.</p> <p>20 A. I think that's what I -- what I found in my</p> <p>21 analysis, yes.</p> <p>22 Q. And the statement of the ASA is that</p> <p>23 statistical significance is not equivalent to</p> <p>24 scientific, human, or economic significance; correct?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 83</p> <p>1 be statistically significant. It may not be the only</p> <p>2 thing you consider, but it's certainly an -- an</p> <p>3 important part of it.</p> <p>4 Q. But for clinical significance, it's not</p> <p>5 necessary to have statistical significance.</p> <p>6 A. Oh, I -- I'm -- no, I --</p> <p>7 Q. Not necessary.</p> <p>8 A. I think it would be important to have</p> <p>9 statistical significance to say that it's</p> <p>10 clinically -- clinically important.</p> <p>11 Q. Do you disagree with the recent statement of</p> <p>12 The American Statistical Association that concludes</p> <p>13 that clinical significance is not determined by</p> <p>14 statistical significance?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 A. I'm not familiar with the particular</p> <p>18 statement that you're saying, but I mean I think</p> <p>19 it's -- I think we're, again, quibbling about --</p> <p>20 I mean I -- I doubt that they're saying</p> <p>21 that -- that when looking at a clinical effect, you</p> <p>22 don't -- you're not interested in whether or not the</p> <p>23 association of the study was statistically</p> <p>24 significant.</p> <p>25 Q. Well I'm not -- I'm not limiting the</p>	<p style="text-align: right;">Page 85</p> <p>1 MR. SACCHET: Okay. We'll take a break.</p> <p>2 (Recess taken.)</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. Dr. Holford, if we could turn back to your</p> <p>5 curriculum vitae, which has been marked as Exhibit 2.</p> <p>6 I don't think you'll need it to answer these</p> <p>7 questions, but in case you do, there it is.</p> <p>8 You are a fellow of The American College of</p> <p>9 Epidemiology; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Does your membership in the college reflect</p> <p>12 your expertise in that subject matter?</p> <p>13 A. Yes.</p> <p>14 Q. And that subject matter is the incidence of</p> <p>15 disease in certain populations; correct?</p> <p>16 A. Well it's -- it's more than just the</p> <p>17 incidence, it's the -- it's a -- a lot of studies of</p> <p>18 etiology of disease.</p> <p>19 Q. Okay. How many members are there in the</p> <p>20 college, do you know?</p> <p>21 A. No, I don't.</p> <p>22 Q. Okay. The other members are presumably</p> <p>23 experts in the field as well; correct?</p> <p>24 A. In different aspects of epidemiology, yes.</p> <p>25 Q. What does it take for one to become the</p>

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<p style="text-align: right;">Page 86</p> <p>1 president of the college?</p> <p>2 A. You have to run for election and be -- get</p> <p>3 the most votes.</p> <p>4 Q. Have you voted in such an election?</p> <p>5 A. I -- I think I voted, yes.</p> <p>6 Q. What are your criteria for voting someone to</p> <p>7 be president?</p> <p>8 A. My view of their scientific standing.</p> <p>9 Q. So the president would have sound scientific</p> <p>10 standing in your view.</p> <p>11 A. Yes. Oh, yeah.</p> <p>12 Q. You're aware that Dr. Samet was elected</p> <p>13 president of the college in 1999; correct?</p> <p>14 A. Yes.</p> <p>15 Q. In that regard you review -- you view Dr.</p> <p>16 Samet as an expert in epidemiology.</p> <p>17 A. I do.</p> <p>18 Q. You're also a member of The American College</p> <p>19 of Statistics; correct?</p> <p>20 A. Well it's The American Statistical</p> <p>21 Association.</p> <p>22 Q. Okay. Thanks for the clarification.</p> <p>23 And I assume the same holds true: if you're</p> <p>24 a member of that association, presumably you're an</p> <p>25 expert in some matter in statistics; correct?</p>	<p style="text-align: right;">Page 88</p> <p>1 My knowledge of what was -- statistical</p> <p>2 methods were used is what's -- is what was in the</p> <p>3 McGovern paper.</p> <p>4 Q. So the Nachtsheim deposition transcript</p> <p>5 played no role in your opinion that you provided in</p> <p>6 your expert report; correct?</p> <p>7 A. Correct.</p> <p>8 Q. You're not aware of whether Professor</p> <p>9 Nachtsheim provided a justification for using</p> <p>10 chi-squared instead of Fisher's exact; are you?</p> <p>11 A. No, I'm not.</p> <p>12 Q. You're not aware of whether Professor</p> <p>13 Nachtsheim continues to stand by the calculations</p> <p>14 that were made in the McGovern study; correct?</p> <p>15 A. I -- I have no idea what -- what his</p> <p>16 opinions are.</p> <p>17 Q. You're not aware of whether Professor</p> <p>18 Nachtsheim commented on the accuracy of Albrecht</p> <p>19 Exhibit 10 or McGovern Exhibit 16; correct?</p> <p>20 A. Correct.</p> <p>21 Q. I apologize if I've already asked the</p> <p>22 question, but you did not review the Moretti study in</p> <p>23 terms of drafting your expert report in this case;</p> <p>24 correct?</p> <p>25 A. Correct.</p>
<p style="text-align: right;">Page 87</p> <p>1 A. That's correct.</p> <p>2 Q. Are you aware that Professor Nachtsheim is</p> <p>3 also a member of the association?</p> <p>4 A. I didn't know that, but --</p> <p>5 Q. You know that Professor Nachtsheim was one</p> <p>6 of the authors of the McGovern study; correct?</p> <p>7 A. Yes.</p> <p>8 Q. So you have no doubt that Professor</p> <p>9 Nachtsheim is an expert in the field of statistics.</p> <p>10 A. Yes, I'm sure he'd have some expertise in</p> <p>11 that.</p> <p>12 Q. You did not review Professor Nachtsheim's</p> <p>13 deposition; correct?</p> <p>14 A. No, I did not.</p> <p>15 Q. So you do not know anything about Dr.</p> <p>16 Samet's testimony regarding the statistical methods</p> <p>17 that were employed in the McGovern study; correct?</p> <p>18 MR. GORDON: Did you mean to say "Samet?"</p> <p>19 MR. SACCHET: No.</p> <p>20 MR. GORDON: You just said "Samet."</p> <p>21 MR. SACCHET: Oh. Thanks, Mr. Gordon.</p> <p>22 Q. You're not aware of what Professor</p> <p>23 Nachtsheim testified about the statistical methods</p> <p>24 used in the McGovern study; correct?</p> <p>25 A. I -- I --</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. Didn't you want to have all of the author</p> <p>2 testimony when making determinations about the</p> <p>3 accuracy of the McGovern study?</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 A. Yeah. I'm not -- all -- all of their</p> <p>7 testimony or all of their work --</p> <p>8 I mean the paper, I think, pretty much</p> <p>9 stands on -- on -- on its own. It justifies what</p> <p>10 it -- what it did and why it did it.</p> <p>11 Q. Well you reviewed the Albrecht testimony as</p> <p>12 it related to the McGovern study; correct?</p> <p>13 A. I did -- I did review it, yes.</p> <p>14 Q. And you relied on that testimony with</p> <p>15 respect to using Albrecht Exhibit 10 --</p> <p>16 A. Yes.</p> <p>17 Q. -- to reanalyze the data; correct?</p> <p>18 A. Yes. Well that's -- that's correct.</p> <p>19 Q. And you also reviewed Mr. McGovern's</p> <p>20 testimony; did you?</p> <p>21 A. Yes.</p> <p>22 Q. Did you review both days of testimony?</p> <p>23 A. I believe I did, yes.</p> <p>24 Q. And you reviewed Mr. Reed's testimony as</p> <p>25 well.</p>

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<p style="text-align: right;">Page 90</p> <p>1 A. Yes.</p> <p>2 Q. Why did you not review Professor</p> <p>3 Nachtschein's testimony?</p> <p>4 A. I don't know that I --</p> <p>5 I just don't -- don't -- don't recall that.</p> <p>6 I -- yeah.</p> <p>7 Q. He's the only professor of statistics that</p> <p>8 was an author of that study; correct?</p> <p>9 A. Apparently, yes.</p> <p>10 Q. Don't you think it would have been helpful</p> <p>11 to review that deposition considering that you</p> <p>12 reviewed the other authors' deposition testimony?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question.</p> <p>15 A. It -- it -- it could have been helpful, but</p> <p>16 I -- I think what --</p> <p>17 The statistical methods that were used were</p> <p>18 pretty well described in the paper.</p> <p>19 Q. But you're not aware of the justifications</p> <p>20 for why particular methods were used according to</p> <p>21 Professor Nachtschein; correct?</p> <p>22 A. I'm not sure what justifications he used,</p> <p>23 but they are commonly-used statistical methods that</p> <p>24 were in that paper, and so I'm -- I would not be --</p> <p>25 You know, it -- it's -- it -- it's fairly</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. Were the other deposition transcripts from</p> <p>2 Mr. Albrecht, Mr. McGovern and Mr. Reed provided to</p> <p>3 you?</p> <p>4 A. Yes.</p> <p>5 Q. And Professor Nachtschein's deposition was</p> <p>6 not provided to you.</p> <p>7 A. I don't recall that it was. I -- it may</p> <p>8 have been, I -- I just -- I'm -- I just don't recall</p> <p>9 it.</p> <p>10 Q. I'm going to put down the guard. I mean</p> <p>11 don't -- don't you find that unusual, that three of</p> <p>12 the authors' deposition transcripts were provided to</p> <p>13 you but the only statistician's deposition transcript</p> <p>14 was not?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 A. These -- yeah, I mean I -- I was --</p> <p>18 The statistical aspects of this study are</p> <p>19 not terribly complicated, frankly.</p> <p>20 Q. You take issue, though, with respect to the</p> <p>21 tabulation of the data; correct?</p> <p>22 A. Oh, it's -- you --</p> <p>23 It's important that you put the right</p> <p>24 numbers down, yeah.</p> <p>25 Q. And Professor Nachtschein could have opined</p>
<p style="text-align: right;">Page 91</p> <p>1 common to use, I mean, basically use chi-square.</p> <p>2 Q. One of your issues with the study is it used</p> <p>3 chi-squared instead of Fisher's exact; correct?</p> <p>4 A. In this particular --</p> <p>5 Yes.</p> <p>6 Q. And you're not aware of perhaps why</p> <p>7 Professor Nachtschein decided to use chi-squared</p> <p>8 instead of Fisher's exact.</p> <p>9 A. Instead of Fish --</p> <p>10 No, I'm not -- I don't -- I don't see why I</p> <p>11 would not -- if he --</p> <p>12 Whatever reasoning he might have had, I</p> <p>13 would -- I would dispute that for reasons that are in</p> <p>14 my report.</p> <p>15 Q. And you've already said that Professor</p> <p>16 Nachtschein is an expert in statistics because he is a</p> <p>17 member of The American Statistical Association;</p> <p>18 correct?</p> <p>19 A. He -- he is an expert. He -- he obviously</p> <p>20 has interest in -- in statistics, --</p> <p>21 Q. Okay.</p> <p>22 A. -- but --</p> <p>23 Q. Did you ask for Professor Nachtschein's</p> <p>24 deposition?</p> <p>25 A. No, I didn't.</p>	<p style="text-align: right;">Page 93</p> <p>1 on the tabulation of the data; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. I -- I suppose he might have. I mean the</p> <p>5 other -- the other authors certainly did.</p> <p>6 Q. And that's why you reviewed their deposition</p> <p>7 testimony; correct?</p> <p>8 A. That's -- that's part of what I -- what I --</p> <p>9 what came out of my review of their testimony, yes.</p> <p>10 Q. Is --</p> <p>11 So everything that's been marked on page 14</p> <p>12 of your report, in addition to the recent Augustine</p> <p>13 study, are the materials that you reviewed in drafting</p> <p>14 your report and providing testimony today.</p> <p>15 A. Well the recent August -- Augustine study I</p> <p>16 saw after --</p> <p>17 Q. Yes.</p> <p>18 A. -- this was submitted, so that's not on here</p> <p>19 because I -- I hadn't seen it when I wrote this.</p> <p>20 Q. But that's the totality of evidence up to</p> <p>21 this point in time.</p> <p>22 A. That's pretty much it, yes. Yes.</p> <p>23 MR. GORDON: I -- I think he also reviewed</p> <p>24 the Samet testimony about the Augustine article.</p> <p>25 THE WITNESS: Oh, I'm sorry, yes.</p>

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<p style="text-align: right;">Page 94</p> <p>1 MR. SACCHET: Okay.</p> <p>2 THE WITNESS: There was also that.</p> <p>3 Q. Okay. So no other articles other than</p> <p>4 what's been listed on page 14.</p> <p>5 A. No.</p> <p>6 Q. And no other deposition transcripts aside</p> <p>7 from Samet and I think you said Augustine.</p> <p>8 A. I saw -- I saw just a couple of pages of --</p> <p>9 of Augustine, but --</p> <p>10 Q. Okay. Did you perform any independent</p> <p>11 investigation outside of what was provided to you?</p> <p>12 A. No.</p> <p>13 Q. So everything that you're relying on is what</p> <p>14 3M provided to you.</p> <p>15 A. That's correct.</p> <p>16 Q. Okay. With respect to the McGovern study,</p> <p>17 I'd like to review that quickly. I assume that we are</p> <p>18 on the same page, doctor, with calling this study "the</p> <p>19 McGovern study," which is the one that you discuss in</p> <p>20 your report; correct?</p> <p>21 A. Yes.</p> <p>22 (Exhibit 13 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. SACCHET:</p> <p>25 Q. We have handed you what has been marked as</p>	<p style="text-align: right;">Page 96</p> <p>1 math, --</p> <p>2 A. Yeah.</p> <p>3 Q. -- or I believe on page 1541 you'll see it</p> <p>4 in the bottom left-hand corner.</p> <p>5 A. Yeah. Okay.</p> <p>6 Yeah, 1066 and 371 are the two groups.</p> <p>7 Q. Which adds up though 1437.</p> <p>8 A. Okay. Yeah, right.</p> <p>9 Q. And the -- the study period was 2.5 years;</p> <p>10 correct?</p> <p>11 A. I think that's right, yes.</p> <p>12 Q. You can look at page 1540 --</p> <p>13 A. Yeah.</p> <p>14 Q. -- on the left-hand side under "Joint</p> <p>15 Infection data."</p> <p>16 A. Right.</p> <p>17 Q. And deep joint infections as opposed to</p> <p>18 superficial or wound infections was the outcome of</p> <p>19 interest; correct?</p> <p>20 A. That's correct.</p> <p>21 Q. And there were three warming phases, there</p> <p>22 was the Bair Hugger period, a transitional period, and</p> <p>23 a conductive warming period; correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And during the Bair Hugger period there was</p>
<p style="text-align: right;">Page 95</p> <p>1 Exhibit 13. The title is "Forced-air warming and</p> <p>2 ultra-clean ventilation do not mix" by McGovern et al;</p> <p>3 correct?</p> <p>4 A. Correct.</p> <p>5 Q. I do not know whether you will need the</p> <p>6 study to answer these questions, but feel free to</p> <p>7 refer to it as you see fit.</p> <p>8 There were two components to this study;</p> <p>9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. There was a study of bubbles in an</p> <p>12 experimental setting, and then there was the</p> <p>13 observational data aspect of the study; correct?</p> <p>14 A. Yes.</p> <p>15 Q. And the first part of the study, which we've</p> <p>16 discussed a little bit, found a significant increase</p> <p>17 in the amount of bubbles over the surgical site in</p> <p>18 this experimental study when the Bair Hugger was used</p> <p>19 compared to a conductive warming device; correct?</p> <p>20 A. That's what they report, yes.</p> <p>21 Q. Okay. And the second part, which involved</p> <p>22 the observational data set, involved 1,437 patients;</p> <p>23 correct?</p> <p>24 A. I think that's right.</p> <p>25 Q. Table II, you might have to do a little</p>	<p style="text-align: right;">Page 97</p> <p>1 a change in the antibiotic; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. The first antibiotic was Gentamicin;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And the second antibiotic was Gentamicin</p> <p>7 plus Teicoplanin.</p> <p>8 A. That's correct.</p> <p>9 Q. Are you comfortable referring to that</p> <p>10 protocol as GenTeic?</p> <p>11 A. Okay.</p> <p>12 Q. There was also a change in the</p> <p>13 thromboprophylaxis.</p> <p>14 A. That's right.</p> <p>15 Q. The first thromboprophylaxis was tinzaparin</p> <p>16 during the Bair Hugger arm of the study; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And in the last six months of the Bair</p> <p>19 Hugger arm there was a change to rivaroxaban; correct?</p> <p>20 A. That's correct.</p> <p>21 Q. Are you okay with referring to rivaroxaban</p> <p>22 as Xarelto?</p> <p>23 A. Okay.</p> <p>24 Q. It's just the pharmaceutical name of -- of</p> <p>25 that thrombo.</p>

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<p style="text-align: right;">Page 98</p> <p>1 And in the Hot Dog period patients went back 2 and received tinzaparin as opposed to Xarelto; 3 correct? 4 A. That's correct. 5 Q. Okay. So results reported in Table II of 6 this study show that three out of 371 patients 7 developed a deep joint infection in 60 days; correct? 8 A. That's correct. 9 Q. And the percentage of that infection rate is 10 .8 percent; correct? 11 A. Correct. 12 Q. As also reported in Table II, 32 out of 13 1,066 patients developed a deep joint infection after 14 receiving the Bair Hugger warming; correct? 15 A. That's correct. 16 Q. The change from the infection rate of the 17 Bair Hugger -- 18 Which is three percent; correct? 19 A. Yes. 20 Q. -- to the .8 percent is a marked decline; is 21 it not? 22 MR. GORDON: Object to the form of the 23 question. 24 A. It -- it is -- it is lower, yes. 25 Q. Would you agree that it's a marked decline?</p>	<p style="text-align: right;">Page 100</p> <p>1 apologize. 2 A. Yeah. It -- it -- it is significant at the 3 five percent level, yes. 4 Q. Okay. So I always say this wrong, but 5 perhaps you can edify me. If you have a statistically 6 significant p-value using a 95 percent or five -- five 7 percent threshold, -- 8 A. Yes. 9 Q. -- does that mean that if you repeated the 10 study a hundred times using the same -- a similar 11 population of patients, that you would expect the same 12 outcome at least 95 -- 95 times out of a hundred? 13 A. No. 14 Q. Okay. What -- 15 So please edify. 16 A. What that means is if -- if there is no 17 association and you repeat the study, you're comparing 18 two groups where there is no effect, then just five 19 percent of the time you will reject the -- you will 20 reject the -- the null hypothesis, which is that there 21 is no effect. 22 Q. Okay. So is another way to think about it 23 is there's a five-percent chance of getting a false 24 positive? 25 A. No, it's not looking at the false positive.</p>
<p style="text-align: right;">Page 99</p> <p>1 MR. GORDON: Object to the form of the 2 question. 3 A. I don't under -- what do you mean by -- 4 What is "marked?" 5 Q. Have you asked Dr. Borak? 6 A. The meaning of -- 7 It's -- it's not a quantitative term that 8 I'm familiar with. 9 Q. So to the extent that Dr. Borak used that 10 language in his report, you wouldn't feel comfortable 11 with the same language. 12 A. I'm not fam -- 13 I have not read his report. I mean it's 14 a -- it's a -- it's a -- it's a substantial -- it's a 15 big decline, yes. 16 Q. A big decline. 17 A. It is a big difference. 18 Q. And the p-value reported in Table II is 19 .024; correct? 20 A. That's -- that is the reported value, yes. 21 Q. And that reported p-value is statistically 22 significant based on the 95 percent confidential 23 interval; correct? 24 A. I would disagree with your language. 25 Q. Okay. It's maybe not meaningful. I</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. Okay. 2 A. It's looking at what's the -- what's the 3 chance that you would see this big of a difference if 4 there was no effect. 5 Q. Okay. Got it. 6 A. And it's only five per -- 7 It's less than five percent, -- 8 Q. Got it. 9 A. -- so that's a fairly rare event. So we're 10 doing this under the null hypothesis, -- 11 Q. Yup. 12 A. -- so therefore we would reject that 13 hypothesis -- 14 Q. Yeah. 15 A. -- and take the alternative. 16 Q. Got it. 17 A. Yeah. 18 Q. And the odds ratio reported in Table II is 19 3.8; correct? 20 A. Yes, I think that's correct. 21 Q. And would you agree with Dr. Borak's 22 statement that that's a significantly increased odds 23 ratio? 24 A. Well there are two -- two parts to that. 25 It -- it is statis -- using the approach reported, it</p>

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<p style="text-align: right;">Page 102</p> <p>1 is statistically significant. The other part of it is 2 what is the magnitude of that effect, and for the 3 magnitude, of course, the point estimate is 3.8, which 4 is a fairly large effect. The -- the confidence 5 interval on the other hand, as they reported here, is 6 1.2 to 12.5, so it's a very broad -- it's over the 7 line of statistical significance, but the precision 8 is -- 9 Well I mean this is a tenfold range for your 10 95 percent confidence interval for the -- for -- for 11 your estimate of what that effect is. 12 Q. And I'll get to the confidence interval 13 later on this afternoon, but with respect to just the 14 odds ratio -- 15 A. Oh, sure. 16 Q. -- of 3.8, do you agree with Dr. Borak that 17 it significantly increased OR. 18 A. Yes. 19 Q. Significantly increased. 20 A. It's increased, yeah. 21 Q. Okay. On page two of your report you 22 provide a calculation that uses different infection 23 data than what was reported in the McGovern study; 24 correct? 25 A. It's different from what's in the paper,</p>	<p style="text-align: right;">Page 104</p> <p>1 it should have been calculated -- attributed to -- to 2 that treatment. 3 Q. So you said it seems that. You're not sure 4 though; right? 5 A. Well it's -- 6 Taking those dates, doing what they said the 7 study was, that's what you get. 8 Q. Okay. 9 A. That's -- that's what I report in here. 10 Q. But you would agree that the data in your 11 report in terms of how many infections were in each 12 arm of the study is different than what -- 13 A. That's correct. 14 Q. -- the author published; correct? 15 A. That's correct. 16 Q. And you just mentioned that with respect to 17 conducting that calculation of the incidence of 18 infection in those Bair Hugger patients and Hot Dog 19 patients, you relied on Albrecht Exhibit 10; correct? 20 A. Yes. 21 MR. GORDON: Object to the form of the 22 question. Misstates his testimony. 23 (Exhibit 14 was marked for 24 identification.) 25 BY MR. SACCHET:</p>
<p style="text-align: right;">Page 103</p> <p>1 yes. 2 Q. So instead of using three Hot Dog infections 3 as reported in the study, your tabulation uses four 4 Hot Dog infections; correct? 5 A. We found the four based on the data in -- 6 well, it's Exhibit -- it's Exhibit 10 of -- 7 Q. Mr. Albrecht. 8 A. -- Albrecht's and also, I mean, there's 9 related data on that that McGovern provided and -- and 10 whatnot. 11 Q. Okay. 12 A. So going back to the -- the raw data, 13 that -- that -- that is the basis of what I report on 14 page two. 15 Q. And you also in that calculation used 31 16 Bair Hugger infections as opposed to the 32 that was 17 reported in the study; correct? 18 A. That's -- that's correct, yeah. 19 Q. And that's -- 20 A. It seems like in that data set there's one 21 observation that occurred during the Hot Dog period 22 that was attributed in the McGovern tabulation to 23 being a -- a Bair Hugger infection when it actually 24 occurred during the Hot Dog period, so it -- based on 25 their description of what the -- what the study was,</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. I understand that there's a lot of pages in 2 front of you, but does this appear to be the document 3 that you reviewed in determining that there were, 4 according to you, one more infection in the Hot Dog 5 group and one less in the Bair Hugger group? 6 A. It -- it -- it appears to be, yes. 7 Q. And this document was provided to you by 3M? 8 A. Yes. 9 Q. Okay. As kind of just a general statistical 10 or epidemiological matter, you need to rely on 11 complete data sets; correct? 12 A. Yes. 13 Q. And if you don't rely on complete data sets, 14 there could be an artifact issue; correct? 15 A. Well -- well there could be -- there could 16 be an error in the calculation that is worth checking. 17 Q. And that would be an artifact; right? 18 A. Okay. Yeah. 19 Q. Could you please turn to the Bates number 20 AUGUSTINE -- which they all share in common -- 5277 21 in the document. 22 MR. GORDON: And the system. 23 MR. SACCHET: Oh, so I can back up. 24 Q. Are you familiar with Bates numbers, doctor? 25 A. The base numbers? No, I'm not sure which</p>

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<p style="text-align: right;">Page 106</p> <p>1 ones you're talking about.</p> <p>2 Q. The Bates number is the number on the bottom</p> <p>3 of the page.</p> <p>4 MR. GORDON: Did you say 5277?</p> <p>5 MR. SACCHET: Yes.</p> <p>6 MR. GORDON: My copy doesn't have one.</p> <p>7 MR. SACCHET: Does yours?</p> <p>8 THE WITNESS: No.</p> <p>9 MR. SACCHET: Mine doesn't either.</p> <p>10 Q. Do you know whether the copy that you had</p> <p>11 had that page?</p> <p>12 A. I assumed it was all there, yeah. I</p> <p>13 didn't --</p> <p>14 Q. Well --</p> <p>15 A. Yeah, I don't -- don't recall.</p> <p>16 Q. Yeah. You didn't look at whether there was</p> <p>17 a gap in the Bates numbers that were included on the</p> <p>18 pages; did you?</p> <p>19 A. No, I didn't.</p> <p>20 Q. Okay. I'm going to try to walk you through</p> <p>21 the sequence in -- of pages here. On 5278 do you see</p> <p>22 the table?</p> <p>23 A. Yes.</p> <p>24 Q. And that table has a list of dates in column</p> <p>25 G?</p>	<p style="text-align: right;">Page 108</p> <p>1 if the pattern repeats itself of those five pages. Is</p> <p>2 the first page a table with a bunch of dates and other</p> <p>3 values?</p> <p>4 A. Yes.</p> <p>5 Q. Is the second table one with a bunch of Ns?</p> <p>6 A. Yes.</p> <p>7 Q. Is the third page, with the AUGUSTINE Bates</p> <p>8 number 005285, a table with null values?</p> <p>9 A. Yeah, mostly null -- N and null. Yeah.</p> <p>10 Q. Yeah. Is the fourth page, which has the</p> <p>11 Bates number AUGUSTINE_0005286, largely a blank table?</p> <p>12 A. Yes.</p> <p>13 Q. And is the fifth page, marked as AUGUSTINE_</p> <p>14 005287, a narrower table that has NOs and in one</p> <p>15 instance a YES?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. I'll represent to you that this</p> <p>18 pattern runs true through the document itself.</p> <p>19 A. Yes.</p> <p>20 Q. But if we could turn back to Bates number</p> <p>21 AUGUSTINE_005278, --</p> <p>22 A. 5278. Okay.</p> <p>23 Q. -- and the missing page that we don't have</p> <p>24 is AUGUSTINE_005277; correct?</p> <p>25 A. Correct.</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Correct.</p> <p>2 Q. Okay. And then the second page is another</p> <p>3 large table of -- mostly ends in no quantitative data;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And then the third page is a similar table,</p> <p>7 but it has kind of these -- a bunch of Ns with null</p> <p>8 values.</p> <p>9 A. Correct.</p> <p>10 Q. Okay. The fourth page is also a large table</p> <p>11 with virtually no data on it.</p> <p>12 A. Correct.</p> <p>13 Q. And the fourth page is a much narrower table</p> <p>14 that, in this instance, documents what appears to be a</p> <p>15 deep joint infection; correct?</p> <p>16 MR. GORDON: You mean the fifth page?</p> <p>17 MR. SACCHET: The fifth page. Thank you,</p> <p>18 Mr. Gordon.</p> <p>19 A. Correct.</p> <p>20 Q. And that page in particular is AUGUSTINE_</p> <p>21 0005282; correct?</p> <p>22 A. AUGUSTINE --</p> <p>23 Q. At the bottom.</p> <p>24 A. Oh, I'm sorry. Yes.</p> <p>25 Q. Okay. Let's turn to the next page and see</p>	<p style="text-align: right;">Page 109</p> <p>1 Q. Okay. So let's flip to AUGUSTINE_005274,</p> <p>2 which is three pages before the document.</p> <p>3 A. Okay.</p> <p>4 Q. And, excuse me, let's actually go to 5273,</p> <p>5 the page before that. That's the table like the other</p> <p>6 pages we've seen that has the dates; correct?</p> <p>7 A. Correct.</p> <p>8 Q. On 5273; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And then on 5274 we've got the big table</p> <p>11 with a bunch of Ns; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And the third page, which is 5275, there are</p> <p>14 kind of the null values and other Ns; right?</p> <p>15 A. Yes.</p> <p>16 Q. Following the same pattern as the other</p> <p>17 pages we've established; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And the fourth page is, like the other</p> <p>20 fourth pages in other sequences, a big table with</p> <p>21 bunches of zeroes; right?</p> <p>22 A. Bunch of blanks.</p> <p>23 Q. Yeah.</p> <p>24 A. Yeah, uh-huh.</p> <p>25 Q. And that's like the fourth page in the other</p>

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<p style="text-align: right;">Page 110</p> <p>1 sequences we went over; correct?</p> <p>2 A. Correct.</p> <p>3 Q. The page that's missing, 5278, is the narrow</p> <p>4 table; correct?</p> <p>5 MR. GORDON: 5277 you mean?</p> <p>6 MR. SACCHET: 5277. I apologize.</p> <p>7 A. That's right.</p> <p>8 Q. And based on the sequence in the other</p> <p>9 documents we looked at, that is the table that has</p> <p>10 information as to whether or not there was a deep</p> <p>11 joint infection; correct?</p> <p>12 A. Correct.</p> <p>13 Q. So this document that you relied on in your</p> <p>14 report was missing the page that had information as to</p> <p>15 whether or not there was a deep joint infection in the</p> <p>16 time period that describes these five pages in the</p> <p>17 table.</p> <p>18 A. I --</p> <p>19 As I -- as I said, I don't -- I don't recall</p> <p>20 going over all of the -- the details in these pages</p> <p>21 and seeing that that was missing.</p> <p>22 Q. So you weren't aware that there was the</p> <p>23 missing page that included infection data regarding</p> <p>24 the use of the Bair Hugger device; correct?</p> <p>25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. And we're missing the page in this document</p> <p>2 to know whether or not there were additional</p> <p>3 infections in the Bair Hugger period; correct?</p> <p>4 A. That --</p> <p>5 Well, that's not in this document, yes. But</p> <p>6 in the file I --</p> <p>7 I mean the numbers on my page two</p> <p>8 essentially correspond to the numbers that are in</p> <p>9 McGovern's paper, so the results I'm getting from my</p> <p>10 tabulation, with the one difference of switching the</p> <p>11 single value -- and if you go to the -- I think it's</p> <p>12 the -- one of the exhibits from the McGovern</p> <p>13 testimony, you can -- you can see where that one</p> <p>14 observation was -- was described as FAW when it should</p> <p>15 have been -- what is -- CFW or -- yeah.</p> <p>16 Q. And we'll get to the McGovern exhibit in a</p> <p>17 couple minutes, --</p> <p>18 A. Yeah.</p> <p>19 Q. -- but --</p> <p>20 A. So we do not -- there's --</p> <p>21 The numbers that we're ending up with</p> <p>22 correspond to what is in the McGovern paper.</p> <p>23 Q. So are you saying you don't feel comfortable</p> <p>24 relying on Albrecht Exhibit 10?</p> <p>25 A. Well --</p>
<p style="text-align: right;">Page 111</p> <p>1 question, assumes facts not in evidence.</p> <p>2 A. I didn't see that there was a -- a -- a -- a</p> <p>3 miss -- a missing page in the -- in the -- the data</p> <p>4 set that I used to analyze.</p> <p>5 Q. Let's go to AUGUSTINE_5273, which was the</p> <p>6 first page of the sequence.</p> <p>7 A. Right.</p> <p>8 Q. The dates that are delineated there are from</p> <p>9 September 2008 to September 26, 2008; correct?</p> <p>10 A. September 8, yeah, twenty --</p> <p>11 Yeah, uh-huh.</p> <p>12 Q. And the Bair Hugger period of this study of</p> <p>13 the McGovern et al paper began in July of 2008;</p> <p>14 correct?</p> <p>15 A. Yes.</p> <p>16 Q. And it ran until February of 2010; correct?</p> <p>17 A. Yes.</p> <p>18 Q. So this table describes operations that</p> <p>19 occurred when using the Bair Hugger in the McGovern</p> <p>20 study; correct?</p> <p>21 A. Correct.</p> <p>22 Q. So if there were an infection that would</p> <p>23 have occurred in this time period, it would have been</p> <p>24 during the Bair Hugger warming period; correct?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 113</p> <p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 A. The -- the data that we're looking at are</p> <p>4 derived from -- are basically from -- from --</p> <p>5 from -- from -- from this, and I'm -- it's based on a</p> <p>6 table from this that I am doing in my analysis.</p> <p>7 Q. And we're missing a page that deals with the</p> <p>8 presence or not of deep joint infection; correct?</p> <p>9 A. The -- the data file that I -- that I'm</p> <p>10 using is these same data that -- that are -- that I</p> <p>11 think are tabulated in this. They're tabulated here.</p> <p>12 Apparently, one of the pages got missed in -- when</p> <p>13 they produced -- produced this. I wasn't -- and I --</p> <p>14 you know, I wasn't shuffling through by hand</p> <p>15 everything here to -- to do the -- to do the</p> <p>16 tabulation.</p> <p>17 Q. So are you relying on McGovern 16 instead of</p> <p>18 this?</p> <p>19 A. No. Because McGovern 16, it includes</p> <p>20 additional detail that -- that corroborate the</p> <p>21 tabulations that were derived from this -- from this</p> <p>22 data set.</p> <p>23 Q. You're aware that this data set was not</p> <p>24 produced by any authors in the study; correct?</p> <p>25 MR. GORDON: Object to the form of the</p>

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<p style="text-align: right;">Page 114</p> <p>1 question, lack of foundation, assumes facts not in 2 evidence. 3 A. I -- I don't -- I don't know who 4 ultimately -- you know, originally produced this. 5 Q. Why does your report on page two say that it 6 was produced by Dr. Scott Augustine in response to a 7 subpoena? Did you write that? 8 A. I -- I did write that. I -- 9 That was my understanding of where the -- 10 where the file came from. 11 Q. Dr. Augustine is not an author of the 12 McGovern study; is he? 13 MR. GORDON: Object to the form of the 14 question, lack of foundation, assumes facts not in 15 evidence. 16 A. He's not listed as an author. 17 Q. His -- 18 A. My understanding is that he had some 19 involvement with -- with this. And I mean his name's 20 at the bottom of this -- of this document that you 21 just gave me. 22 Q. So do you feel comfortable relying on 23 documents produced by Dr. Augustine? 24 MR. GORDON: Object to the form of the 25 question.</p>	<p style="text-align: right;">Page 116</p> <p>1 A. No, I didn't. 2 Q. Do you know whether or not Augustine was 3 responsible for collecting the data that was 4 eventually used in the McGovern study? 5 A. I don't know that he did. I -- I'm sure he 6 delegated that to someone, it must be in all 7 likelihood, but I really don't know how this was -- 8 was -- who all as involved with producing it. 9 Q. You don't know that Dr. Reed, an orthopedic 10 consultant in the U.K., was the individual responsible 11 for collecting the data? 12 A. I know that Dr. Reed was involved with it. 13 The -- the management organization of that is -- is -- 14 is something I don't know. 15 Q. Would knowing that Dr. Reed was in charge of 16 collecting the data instead of Dr. Augustine give you 17 any pause as to whether this is the final data set? 18 MR. GORDON: Object to the form of the 19 question. 20 A. I have -- 21 I mean if -- if Dr. Reed produced it and -- 22 and Dr. Augustine supplied it, I -- I'm taking the 23 values as they are. I mean I -- I was just analyzing 24 the data that I was -- that I was shown. 25 Q. Has anyone ever asked you for data based on</p>
<p style="text-align: right;">Page 115</p> <p>1 A. I don't -- don't re -- 2 I -- I'm not -- I'm not sure I understand 3 what you're -- what you're asking. 4 Q. Well you just told me that this is produced 5 by Augustine and you're relying on Exhibit 10. 6 A. I mean Augustine's name is on it. 7 Q. Okay. 8 A. I don't know that he sat there in front of 9 the computer and produced it. 10 Q. So when you say it was produced by Dr. Scott 11 Augustine in response to a subpoena, you don't know 12 whether that's right or wrong. 13 A. I -- I'm basing this on -- on what I 14 understand -- what the -- what -- what I was given to 15 understand of where the data came from that I was 16 using in my analysis. 17 Q. Who gave you that understanding? 18 A. When I was talking to the people that -- 19 with 3M. 20 Q. So you relied on 3M's statement that this 21 was produced by Dr. Augustine and you accepted that 22 statement. 23 A. Yes, correct. 24 Q. Did you perform any independent research to 25 determine whether that was true or false?</p>	<p style="text-align: right;">Page 117</p> <p>1 a published cit -- an article that you published? 2 A. Yes. 3 Q. And did you provide the data? 4 A. Very often it's -- I'm -- 5 I'm often collaborating with another 6 investigator, so -- so the -- I would usually go to -- 7 go to the co-author who owned the data set and they 8 would be involved with the decision on whether or not 9 to provide it. 10 Q. You'd go to a co-author. 11 A. Yes. Well it's often the main author of 12 the -- of the paper. 13 Q. Reed was an author of the -- 14 A. Yes. 15 Q. -- of the article; right? 16 A. That's right, he was the senior author. 17 Q. Did you do any investigation to determine 18 whether Mr. Reed produced a data set? 19 A. No, I didn't. 20 Q. So you don't know whether or not Mr. Reed 21 produced the data set as an author of the study that 22 corroborates the data noted in the McGovern study. 23 A. I don't -- don't know that the -- that 24 the -- that -- that that's what -- what transpired. 25 Q. You didn't attempt to determine that though.</p>

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<p style="text-align: right;">Page 118</p> <p>1 A. No, I didn't.</p> <p>2 Q. And you agree with me that Augustine is not</p> <p>3 a noted author on the study; correct?</p> <p>4 A. He is not. He is not listed as an author,</p> <p>5 yes.</p> <p>6 Q. So you relied on a third party's production</p> <p>7 of a data set with respect to the McGovern study.</p> <p>8 A. Well while he's not an author, I don't know</p> <p>9 if he was involved in fact.</p> <p>10 Q. So you don't know whether he was involved,</p> <p>11 but you still relied on his data set.</p> <p>12 A. Well he had some involvement with -- with</p> <p>13 this -- with this group. I think --</p> <p>14 Q. Does it say that on the study?</p> <p>15 A. I mean where --</p> <p>16 I forget where the funding comes from.</p> <p>17 Q. The last page of the study will tell you if</p> <p>18 there were any benefits. The very last page, very</p> <p>19 last page. Anything say Augustine?</p> <p>20 A. I don't think --</p> <p>21 I don't see anything that says Augustine,</p> <p>22 I -- but that was not the point that I was -- was</p> <p>23 making. I'm not sure where the funding for this work</p> <p>24 came from.</p> <p>25 Q. So you have no basis to know whether or not</p>	<p style="text-align: right;">Page 120</p> <p>1 saying.</p> <p>2 Q. Where did you get the idea?</p> <p>3 A. One of the -- one of the articles -- one of</p> <p>4 the things that I've read -- that I read in preparing</p> <p>5 this report.</p> <p>6 Q. One of the things in the 19 sources listed</p> <p>7 on Ex -- on page 14 of your report?</p> <p>8 A. I believe it was somewhere in there, yes,</p> <p>9 but --</p> <p>10 I mean Albrecht, as I understand it, is --</p> <p>11 was -- is an Augustine -- is working for Augustine.</p> <p>12 Q. Does it say that on the paper?</p> <p>13 A. It doesn't say that on the paper, but --</p> <p>14 Q. You're assuming that to be true.</p> <p>15 A. I think it says that in --</p> <p>16 I think Albrecht says -- said that in his --</p> <p>17 his deposition.</p> <p>18 Q. Are you sure?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. I would have to review his testimony again,</p> <p>22 but it -- it -- it has appeared many -- in -- in</p> <p>23 many -- many things that they -- they are -- they</p> <p>24 are -- they are together, and --</p> <p>25 Q. 3M told you this.</p>
<p style="text-align: right;">Page 119</p> <p>1 the funding came from Augustine; correct?</p> <p>2 A. Well as I say, I --</p> <p>3 Oh, I don't know.</p> <p>4 Q. I'll represent to you that there's no</p> <p>5 mention of Augustine in the McGovern study. You're</p> <p>6 not going to find it.</p> <p>7 A. There -- there is -- there is not. I -- I</p> <p>8 have acknowledged that there's no -- there's no</p> <p>9 specific reference to -- to Augustine. However, I</p> <p>10 believe he did have some -- some involvement with</p> <p>11 the -- the production of this work.</p> <p>12 Q. Have you reviewed the Augustine deposition?</p> <p>13 A. I've seen some of it. Not the whole thing.</p> <p>14 Q. Did Augustine's deposition testimony</p> <p>15 corroborate the fact that he was involved in this</p> <p>16 study, the McGovern study?</p> <p>17 A. As I say, I don't -- I haven't seen the</p> <p>18 whole -- whole of the deposition.</p> <p>19 Q. So you have no basis to conclude that</p> <p>20 actually Augustine was involved in the McGovern study.</p> <p>21 A. Well as I -- as I say, I -- there was --</p> <p>22 There is this issue of where some of the</p> <p>23 funding was coming from for doing the McGovern study,</p> <p>24 and I'm not putting my fingers on it right -- right at</p> <p>25 the moment, so it was part of what I'm -- what I'm</p>	<p style="text-align: right;">Page 121</p> <p>1 A. Well I --</p> <p>2 Q. You said that earlier, five minutes ago.</p> <p>3 A. I --</p> <p>4 They -- they -- they've -- they've said</p> <p>5 that. I said -- as I say, I've also -- I've read it</p> <p>6 in either a defi -- a deposition or one of the other</p> <p>7 things that was -- that -- that I -- that I read, and</p> <p>8 maybe in one of the other papers or something like</p> <p>9 that.</p> <p>10 Q. So you said you read Mr. Albrecht's</p> <p>11 deposition; correct?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And are you familiar with the fact</p> <p>14 that in Mr. Albrecht's deposition he said that the</p> <p>15 data set that was analyzed in terms of conducting this</p> <p>16 study contains three infections in the Hot Dog period?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, misstates the testimony.</p> <p>19 A. I -- I don't recall exactly what he said.</p> <p>20 Q. So you have no recollection as to whether</p> <p>21 Mr. Albrecht actually did say that the data set</p> <p>22 contained three infections for the Hot Dog period.</p> <p>23 A. I don't remember that.</p> <p>24 Q. Well you rely on Mr. Albrecht's testimony in</p> <p>25 determining that Albrecht Exhibit 10 in fact is the</p>

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<p style="text-align: right;">Page 122</p> <p>1 final data set; correct?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. I -- I don't know that this is the data</p> <p>5 set --</p> <p>6 I mean the numbers don't agree with what was</p> <p>7 tabulated in the -- in the -- in -- in the McGovern</p> <p>8 paper, --</p> <p>9 Q. Okay.</p> <p>10 A. -- so I mean I'm not sure where Albrecht did</p> <p>11 the tab -- how -- how Albrecht did -- did the</p> <p>12 tabulation.</p> <p>13 Q. But you rely on Mr. Albrecht's testimony</p> <p>14 to -- in relying on using Exhibit 10; correct?</p> <p>15 A. Using Exhibit 10. But then when you</p> <p>16 tabulate Exhibit 10, you don't get what's in the</p> <p>17 paper.</p> <p>18 Q. Yeah. So you don't know whether Exhibit 10</p> <p>19 is the final data set.</p> <p>20 A. It --</p> <p>21 I don't know that it is the data set that he</p> <p>22 used with this paper or --</p> <p>23 Maybe he made a mistake in the tabulation.</p> <p>24 I don't know.</p> <p>25 Q. Mr. -- or Dr. Borak doesn't conclude that it</p>	<p style="text-align: right;">Page 124</p> <p>1 A. Yes.</p> <p>2 Q. And Mr. Albrecht responds, "I would have to</p> <p>3 physically count these, but that's not what our data</p> <p>4 set says here. The data set that was analyzed there</p> <p>5 was three."</p> <p>6 A. Yes.</p> <p>7 Q. Are you aware that Mr. Albrecht testified</p> <p>8 that the data set that was analyzed had three deep</p> <p>9 joint infections instead of the four that Mr. Gordon</p> <p>10 had asked about?</p> <p>11 A. That's what -- that's what he's saying here,</p> <p>12 and that corresponds to the --</p> <p>13 Q. The study.</p> <p>14 A. -- the -- the -- the -- the Table -- the</p> <p>15 Table II in this -- in the paper.</p> <p>16 Q. But in your report you say that the results</p> <p>17 by McGovern are incorrect because they arise from an</p> <p>18 incorrect tabulation error; an error is recognized in</p> <p>19 the deposition by Albrecht.</p> <p>20 A. You're looking at one piece of it here.</p> <p>21 There's elsewhere that he -- that -- that he talks</p> <p>22 about a -- that -- that there were -- there was</p> <p>23 apparently an error that they recognized later.</p> <p>24 Q. You think Mr. Albrecht said that?</p> <p>25 A. I thought he did somewhere. I -- I don't</p>
<p style="text-align: right;">Page 123</p> <p>1 was the final data set; does he?</p> <p>2 A. I don't know.</p> <p>3 MR. GORDON: Object to the form of the</p> <p>4 question, lacks foundation.</p> <p>5 Q. He called it the apparent data set; doesn't</p> <p>6 he?</p> <p>7 MR. GORDON: Same objection.</p> <p>8 A. As I say, I have not -- I have not seen his</p> <p>9 report.</p> <p>10 Q. Okay.</p> <p>11 (Exhibit 15 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Exhibit 15 is the October 7, 2016 deposition</p> <p>15 of Mr. Albrecht; correct, Dr. Holford?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay. If you could please turn to page 158</p> <p>18 of the transcript, which is page 41 at the bottom. Do</p> <p>19 you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Mr. Gordon asked, "If you count the</p> <p>22 infections for that time period, June 1st 2010, to</p> <p>23 December 31st, 2010, there are actually four,</p> <p>24 correct?"</p> <p>25 Do you see that question?</p>	<p style="text-align: right;">Page 125</p> <p>1 remember exactly where -- where it is.</p> <p>2 Reed said it.</p> <p>3 Q. This is Mr. Albrecht. Do you think Mr.</p> <p>4 Albrecht said there was an error?</p> <p>5 A. I seem to recall he -- that -- that there</p> <p>6 was. I don't remember exactly where -- where it is.</p> <p>7 It's a fairly long report.</p> <p>8 Q. Let's keep going then. If you can go to</p> <p>9 internal page 142, page 37 at the bottom, line 16, Mr.</p> <p>10 Gordon asked, "I have something that's going to help.</p> <p>11 But first I want to establish that -- that is a</p> <p>12 printout of the data that Dr. Reed would have provided</p> <p>13 to you and from which you generated your statistical</p> <p>14 analysis that became the observational component of</p> <p>15 Exhibit 8."</p> <p>16 Do you see that question?</p> <p>17 A. Yes.</p> <p>18 Q. I'll represent to you that Exhibit 8 is the</p> <p>19 McGovern study --</p> <p>20 A. Okay.</p> <p>21 Q. -- and I'll also represent to you that the</p> <p>22 data set that Mr. Gordon is referring to is Albrecht</p> <p>23 Exhibit 10.</p> <p>24 A. Okay.</p> <p>25 Q. The answer is, "I'm assuming, but there's no</p>

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<p style="text-align: right;">Page 126</p> <p>1 way for me to verify something like this." 2 A. Okay. 3 Q. So Mr. Albrecht didn't know whether or not 4 Albrecht Exhibit 10 was the final data set, correct, 5 based on this testimony? 6 A. I -- I -- 7 Yeah. Apparently, yeah. 8 Q. But you have concluded that, based on Mr. 9 Albrecht's testimony, that Albrecht Exhibit 10 is the 10 final data set; is that correct? 11 MR. GORDON: Object to the form of the 12 question, misstates his test -- misstates prior 13 testimony. 14 Q. Is your testimony not that Albrecht Exhibit 15 10 is the final data set? 16 MR. GORDON: Same objection. 17 A. I don't -- I don't -- 18 I'm taking Exhibit 10 as it -- as it -- as 19 it is. I mean what -- 20 What do you mean by "final data set?" 21 Q. Well you've already said that the data set 22 that is in Albrecht 10 is not the data that was in the 23 study; correct? 24 A. A tabulation based on -- based on that -- 25 that data set doesn't agree with the paper.</p>	<p style="text-align: right;">Page 128</p> <p>1 A. I don't know what Mr. Gordon knows or 2 doesn't know about that. 3 Q. Let's look at page 163, which is 42 at the 4 bottom. Are you there, doctor? 5 A. Okay. 6 Q. Line 17, Mr. Gordon asks -- or states, "And 7 I want to make it very clear, I have no idea if 8 Exhibit 10 is the original data" -- 9 Albrecht answers: "I don't either." 10 Do you see that? 11 A. Okay. 12 Q. So Mr. Gordon doesn't know if it's the final 13 data set, Mr. Albrecht doesn't know whether it's the 14 final data set, Mr. Borak in his report uses the word 15 "apparent" data set, you don't know whether it's the 16 final data set -- 17 A. Well the question is not "final," question 18 is "original." 19 Q. Okay. So let's say the original data set. 20 A. Okay. 21 Q. Mr. Gordon doesn't know if Exhibit 10 is the 22 original data set. 23 A. Okay. 24 Q. Mr. Albrecht also doesn't know whether 25 Exhibit 10 is the original data set.</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Yeah. 2 A. Yeah. 3 Q. And Mr. Albrecht in this testimony is saying 4 he doesn't know whether it's the final data set. 5 A. Okay. 6 Q. And Mr. Albrecht also said in the testimony 7 we read a moment ago that there were three infections 8 in the Hot Dog arm that were analyzed with respect to 9 the paper; correct? 10 A. That's -- 11 He's, I assume, re -- reporting back what -- 12 what was actually published in the paper, what this 13 tabulation that's in the paper showed. 14 Q. He says the data set that was analyzed there 15 was three. 16 A. So what is he referring -- 17 When he says "data set," what does he mean? 18 I don't know quite what he -- what he's referring to. 19 Is he referring to the data -- the tabulation that was 20 made from the data, or is he talking about the -- the 21 original file? 22 Q. You're aware that not even Mr. Gordon knows 23 whether Exhibit 10 is the final data set; correct? 24 MR. GORDON: Object to the form of the 25 question, lack of foundation.</p>	<p style="text-align: right;">Page 129</p> <p>1 A. Yeah. 2 Q. Mr. Borak also doesn't know whether Exhibit 3 10 is the original data set. 4 A. Okay. 5 Q. And you don't know. 6 A. I don't. 7 Q. To the extent that you rely on Albrecht 8 Exhibit 10, not knowing whether or not it's the 9 original data set, it could be a data artifact issue; 10 could it not? 11 MR. GORDON: Object to the form of the 12 question. 13 A. If -- if there's an error in -- in -- 14 I mean if -- if the file is not the correct 15 data, then there -- there could be -- there -- there 16 would be a problem with -- with the analysis. 17 Q. And -- and you don't know whether or not 18 there is a problem with the data. 19 A. I don't know. I don't know if there is or 20 if there is not. 21 Q. You know that there's a missing page. 22 A. You -- 23 There is one missing page. 24 Q. You know that the missing page contains or 25 may not contain information regarding deep joint</p>

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<p style="text-align: right;">Page 130</p> <p>1 infection during the Bair Hugger study period; 2 correct? 3 A. It was -- 4 I wasn't looking at the individual pages, as 5 I've -- as I've said, -- 6 Q. Yeah. 7 A. -- and -- and my under -- I -- 8 I don't know if this is the same data set 9 that -- that Albrecht was -- was looking at when he 10 did the -- his -- his calculations. 11 Q. Thank you. 12 Do you have any other reason to assume that 13 Albrecht Exhibit 10 is the original or final data set? 14 MR. GORDON: Object to the form of the 15 question. 16 A. I mean why is Exhibit 10 as part of the 17 Albrecht testimony? 18 Q. Why is it? 19 A. Yeah. How did it get there? 20 Q. Mr. Gordon marked -- 21 A. Okay. 22 Q. -- Exhibit 10 at the deposition. 23 A. And I mean the assumption is is that that is 24 the data on which this is based. 25 Q. You're making that assumption even though</p>	<p style="text-align: right;">Page 132</p> <p>1 after that? It says dash -- 2 MR. SACCHET: Dash. 3 MR. GORDON: -- and continues on with the 4 rest of what I said. 5 MR. SACCHET: -- "or the -- the newer data 6 that's slightly conflicted." 7 Q. Does that change your mind? 8 A. What is the question? 9 Q. The question is: Mr. Albrecht has said that 10 there was three infections in the Hot Dog period based 11 on the data that was analyzed. 12 A. Yes. 13 Q. Mr. Gordon has said he doesn't know if 14 Exhibit 10 is the original data or the newer data 15 that's slightly conflicted. 16 A. Yes. 17 Q. Dr. Borak has said that it apparently could 18 be. 19 A. Yes. 20 Q. You just told me that you're assuming 21 Albrecht Exhibit 10 is the final data set. 22 MR. GORDON: I object to the form of the 23 question. 24 A. Well I'm -- I'm -- that -- 25 Exhibit 10 is the data on which I did the</p>
<p style="text-align: right;">Page 131</p> <p>1 Mr. Albrecht has said that the data set that was 2 analyzed, there was three deep joint infections. 3 A. Yes. 4 Q. You're making that assumption even though 5 Mr. Gordon said that Exhibit 10, he didn't know 6 whether it was the original data set. 7 MR. GORDON: You're -- you're actually -- 8 You're reading only a portion of the 9 testimony and you're -- 10 MR. SACCHET: I think you're testifying 11 right now, Mr. Gordon. 12 MR. GORDON: Well no. I mean -- 13 But come on. 14 MR. SACCHET: I'm -- 15 MR. GORDON: If you're going to quote me, 16 quote what I said; don't make -- don't -- don't -- 17 MR. SACCHET: Okay. 18 MR. GORDON: -- don't screw up the record by 19 selectively quoting half of what I said. 20 MR. SACCHET: Yeah. I'll read the sentence. 21 MR. GORDON: Read the whole sentence. 22 MR. SACCHET: "And I want -- I want to make 23 it very clear, I have no idea if Exhibit 10 is the 24 original data" -- 25 MR. GORDON: And you see the thing it says</p>	<p style="text-align: right;">Page 133</p> <p>1 analysis, -- 2 Q. Okay. 3 A. -- so in -- 4 The total number of infections in my table 5 exactly -- are exactly the same as what are in 6 McGovern's paper. 7 Q. Okay. Do you rely on anything else to 8 conclude that Albrecht Exhibit 10 is the original 9 data? 10 MR. GORDON: Objection -- 11 Q. That's -- that's -- that's the scope of the 12 question. 13 MR. GORDON: Objection, asked and answered. 14 Q. Do you rely on anything else? 15 MR. GORDON: Objection, asked and answered. 16 He's also testified the other things he relied on. 17 MR. SACCHET: I don't recall the other 18 testimony. I'm not -- I'm not -- 19 MR. GORDON: All right. Fair enough. 20 A. I mean I -- I've -- I'm assuming that those 21 are -- 22 The data that -- that formed the basis of -- 23 of that -- of the McGovern paper, that they're in -- 24 that they're in that file. 25 Q. I'm going to ask the question again. Do you</p>

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<p style="text-align: right;">Page 134</p> <p>1 rely on anything else in making that assumption?</p> <p>2 A. Well I've --</p> <p>3 There are other parts of the data that have</p> <p>4 been given as some of the other -- other evidence.</p> <p>5 Q. What?</p> <p>6 A. Well there's a list of -- of the infections</p> <p>7 that I think McGovern --</p> <p>8 Q. Okay.</p> <p>9 A. -- provided, the evi -- well I think</p> <p>10 it's -- I think it was Exhibit 16 in his -- his</p> <p>11 deposition.</p> <p>12 Q. Okay.</p> <p>13 A. And, you know, it's -- it's a different</p> <p>14 file. There are differences in there, differences in</p> <p>15 the way the dates are recorded because we're dealing</p> <p>16 with the way the Brits give dates and the way we give</p> <p>17 dates in the U.S. and things like that. But you can</p> <p>18 match up the -- those two -- two files and they -- you</p> <p>19 know, they -- they agree. And so it -- that has given</p> <p>20 me more confidence that the data that we're looking --</p> <p>21 that I'm looking at really corresponds to the same</p> <p>22 data --</p> <p>23 Q. Okay.</p> <p>24 A. -- that -- that forms the basis of the --</p> <p>25 the report in McGovern.</p>	<p style="text-align: right;">Page 136</p> <p>1 A. Correct.</p> <p>2 Q. That's a number of years after the</p> <p>3 publication of the McGovern study; correct?</p> <p>4 A. Okay. Yeah. Yes, it is.</p> <p>5 Q. And the first paragraph says, "Below is the</p> <p>6 analysis source code and data supporting the</p> <p>7 publication Forced-air warming linked to</p> <p>8 periprosthetic total joint replacement infections.</p> <p>9 This s an R-markdown document, so it can be run</p> <p>10 directly in the R-Console to produce -- to reproduce</p> <p>11 the results." Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And then the next title is "Raw Data" and it</p> <p>14 says, "The raw infection data by hospital is, colon;"</p> <p>15 correct? That's -- that's what it says, "The raw</p> <p>16 infection data by hospital is, colon."</p> <p>17 A. Yes.</p> <p>18 Q. And there's some quotes.</p> <p>19 If you look on the fourth line of that we</p> <p>20 see "c(10, 11, 10, 21, 3, 32);" correct?</p> <p>21 A. Yes.</p> <p>22 Q. And then we see "NonInfections equal c(1087,</p> <p>23 378, 1087, 656, 368, 1034)." Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. Do the numbers 3, 32, 368 and 1034 ring a</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. So anything else in addition to McGovern 16?</p> <p>2 MR. GORDON: Again, asked and answered.</p> <p>3 A. Yeah. Anything --</p> <p>4 It's 10, 16 and -- well, an analysis of</p> <p>5 those. I'm not recalling other sources at the moment,</p> <p>6 but --</p> <p>7 Q. Okay. Thank you. That answers the</p> <p>8 question.</p> <p>9 A. Yeah.</p> <p>10 Q. Before we get to McGovern 16, I'd like to</p> <p>11 show you a few additional documents.</p> <p>12 (Exhibit 16 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. SACCHET:</p> <p>15 Q. Have you seen this document before,</p> <p>16 Professor Holford?</p> <p>17 A. I don't recall seeing this.</p> <p>18 Q. Okay. It has been produced by Mr. Albrecht</p> <p>19 based on the Bates number in the bottom right-hand</p> <p>20 corner; correct? It --</p> <p>21 The bottom right-hand Bates number has the</p> <p>22 prefix "Albrecht."</p> <p>23 A. Oh, I'm sorry. Yes. Yes.</p> <p>24 Q. And the top of the page is entitled</p> <p>25 "LogisticRegression, Mark Albrecht, March 11, 2016."</p>	<p style="text-align: right;">Page 137</p> <p>1 bell?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. No.</p> <p>5 Q. The numbers 3 and 32 are not the same</p> <p>6 numbers that were used in the McGovern publication</p> <p>7 with respect to the total number of infections in the</p> <p>8 Hot Dog arm versus the Bair Hugger arm?</p> <p>9 A. Which --</p> <p>10 I don't understand what you're asking.</p> <p>11 Q. Okay. In the Bair Hugger period, how many</p> <p>12 infections did the authors report with respect to the</p> <p>13 Hot Dog, the authors report in Table II?</p> <p>14 A. Table II.</p> <p>15 Q. Did they report three in Table II, Hot Dog</p> <p>16 infections?</p> <p>17 A. Yeah.</p> <p>18 Q. Okay. How many Bair Hugger infections did</p> <p>19 they report in the McGovern study?</p> <p>20 A. Thirty-two.</p> <p>21 Q. Is that the same number that we see here?</p> <p>22 A. Oh, oh, I see. This is --</p> <p>23 I'm -- I'm sorry, I don't -- I'm not really</p> <p>24 understanding this code.</p> <p>25 Okay. So what is this c?</p>

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<p style="text-align: right;">Page 138</p> <p>1 Q. "Center" perhaps.</p> <p>2 A. No. I think it's a vector usually in R,</p> <p>3 it's a vector and it --</p> <p>4 Q. My -- my -- my question --</p> <p>5 MR. GORDON: Counsel, I mean, you know --</p> <p>6 A. I don't know what --</p> <p>7 MR. SACCHET: Corey, again it's a speaking</p> <p>8 objection. If you want to object, go for it.</p> <p>9 MR. GORDON: Yeah. If you're representing</p> <p>10 this has anything to do with the McGovern paper --</p> <p>11 MR. SACCHET: Yeah?</p> <p>12 MR. GORDON: -- as opposed to what the</p> <p>13 testimony was, which was this was what turned into the</p> <p>14 Augustine -- recently published Augustine paper, you</p> <p>15 know, you've got -- you've got an obligation to --</p> <p>16 to -- to be truthful.</p> <p>17 MR. SACCHET: I'm look -- I --</p> <p>18 My questions are solely about the numbers.</p> <p>19 Q. Professor Holford, were there three</p> <p>20 infections in the Hot Dog period in the McGovern</p> <p>21 study --</p> <p>22 A. Looking at the paper, yes.</p> <p>23 Q. -- as reported in Table II?</p> <p>24 A. As reported in Table II, yes.</p> <p>25 Q. Were there 32 infections as reported in</p>	<p style="text-align: right;">Page 140</p> <p>1 MR. GORDON: I'm going to need a quick break</p> <p>2 in the near future, --</p> <p>3 MR. SACCHET: Okay.</p> <p>4 MR. GORDON: -- whenever it's convenient.</p> <p>5 MR. SACCHET: Okay. Take about five minutes</p> <p>6 if you don't mind.</p> <p>7 MR. GORDON: Right now?</p> <p>8 MR. SACCHET: Just in five minutes.</p> <p>9 MR. GORDON: Oh, that's fine.</p> <p>10 (Exhibit 17 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. SACCHET:</p> <p>13 Q. This is a document with a subject line "Full</p> <p>14 workup of the stats you requested;" correct?</p> <p>15 A. Yes.</p> <p>16 Q. It's been previously marked as McGovern 23;</p> <p>17 correct?</p> <p>18 A. I don't know where you're getting that from.</p> <p>19 Q. The bottom right of the page, there's a</p> <p>20 stamp there and it says Exhibit --</p> <p>21 A. Oh, I see.</p> <p>22 Q. -- Exhibit McGovern 23.</p> <p>23 A. Yeah.</p> <p>24 Q. Have you seen this document before?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 139</p> <p>1 Table II from the Bair Hugger period?</p> <p>2 A. That's correct.</p> <p>3 Q. Were there 368 non-infections in the Hot Dog</p> <p>4 period reported in the McGovern study?</p> <p>5 A. Yes.</p> <p>6 Q. Were there a hundred and -- 1,034 non-</p> <p>7 infections reported in the Bair Hugger -- in the</p> <p>8 McGovern study with respect to the Bair Hugger arm?</p> <p>9 A. Yes.</p> <p>10 Q. These numbers are the same as what was</p> <p>11 reported in the Bair Hugger study, the numbers are the</p> <p>12 same -- it's a simple question -- as reported in the</p> <p>13 McGovern study.</p> <p>14 A. The last -- the last two -- two columns of</p> <p>15 this vector do correspond to that. I don't know what</p> <p>16 the other numbers that are there correspond to. I</p> <p>17 don't know what the 10 --</p> <p>18 The 1087, for example, what is that?</p> <p>19 Q. I'm not asking about those numbers.</p> <p>20 A. Well I have to understand when I'm reading</p> <p>21 someone's code. I don't understand what it's</p> <p>22 referring to.</p> <p>23 Q. And the date is March 11, 2016; correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. This was a document that was --</p> <p>2 I'll represent to you this is a document</p> <p>3 that was marked at the McGovern deposition.</p> <p>4 You reviewed other exhibits from the</p> <p>5 McGovern deposition; correct?</p> <p>6 A. I looked at, I think, some of them, yeah.</p> <p>7 Q. One of them was McGovern Exhibit 16;</p> <p>8 correct?</p> <p>9 A. Oh. Yes, I did.</p> <p>10 Q. But you didn't see this one.</p> <p>11 A. No, I didn't look at this one.</p> <p>12 Q. Did you get all of the exhibits from these</p> <p>13 depositions or just a select handful?</p> <p>14 A. I think they were all there. I didn't -- I</p> <p>15 didn't do an audit to check, but --</p> <p>16 Q. How did you determine which ones to look at</p> <p>17 and which ones not to look at?</p> <p>18 A. It was what was most relevant to the</p> <p>19 analysis that I was doing.</p> <p>20 Q. How did you make that determination?</p> <p>21 A. Well I was -- figured out what I was</p> <p>22 interested in for that particular part of the report I</p> <p>23 was working on.</p> <p>24 Q. Okay. Let's see if this piques your</p> <p>25 interest. The first e-mail is dated November 29th,</p>

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<p style="text-align: right;">Page 142</p> <p>1 2011; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And that is after publication of the</p> <p>4 McGovern study; correct?</p> <p>5 A. I believe so, yes.</p> <p>6 Q. Okay. And in the e-mail on November 30th,</p> <p>7 2011 from Mike Reed to Mark Albrecht, the text states,</p> <p>8 "Mark</p> <p>9 "This is great. I am very grateful.</p> <p>10 So - for clarity - this chart is the same as</p> <p>11 the one in our paper but with longer follow up?"</p> <p>12 Do you see that?</p> <p>13 A. Okay. Yes.</p> <p>14 Q. And then the last line says, "You are 3.6</p> <p>15 times more likely to get an infection on FAW than</p> <p>16 CFW?" Correct?</p> <p>17 Last line of that same paragraph.</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Now if we turn the page, Table 1 does</p> <p>20 in fact look like Table II in the McGovern study;</p> <p>21 correct?</p> <p>22 A. It looks like it, yes.</p> <p>23 Q. Okay. Let's look at the number of patients</p> <p>24 developing infection in the conductive fabric warming</p> <p>25 group. Do you see the number seven?</p>	<p style="text-align: right;">Page 144</p> <p>1 A. I have 32.</p> <p>2 Well wait, I'm sorry. Yeah, 31, that's</p> <p>3 right.</p> <p>4 Q. This is two more.</p> <p>5 A. It is two more.</p> <p>6 Q. And the percent of infection is 3.1 in the</p> <p>7 forced-air group; correct?</p> <p>8 A. Yes.</p> <p>9 Q. That is in fact higher than the percent that</p> <p>10 was reported in the study; correct?</p> <p>11 A. Yes.</p> <p>12 Q. That's higher than the percent that you use</p> <p>13 in your report; correct?</p> <p>14 A. Yes.</p> <p>15 Q. Do you have any basis to conclude that this</p> <p>16 data is not the final data set?</p> <p>17 MR. GORDON: Which data?</p> <p>18 MR. SACCHET: The numbers reported here.</p> <p>19 MR. GORDON: In --</p> <p>20 A. What do you mean by "final data set?" I</p> <p>21 mean --</p> <p>22 MR. GORDON: -- Exhibit 17.</p> <p>23 A. This is very different from --</p> <p>24 It's not the data set that appears in</p> <p>25 McGovern.</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Yes.</p> <p>2 Q. And the percentage .9?</p> <p>3 A. Yes.</p> <p>4 Q. And then there were 792 of whom did not</p> <p>5 develop an infection; correct?</p> <p>6 A. Yes.</p> <p>7 Q. That's approximately double the amount of</p> <p>8 patients that were originally analyzed in the Bair</p> <p>9 Hugger period; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. So this appears to be an extended</p> <p>12 data set; correct?</p> <p>13 A. It appears that they've extended the</p> <p>14 conductive fabric, --</p> <p>15 Q. Okay.</p> <p>16 A. -- yeah.</p> <p>17 Q. Let's look at the forced-air group. How</p> <p>18 many individuals developed an infection?</p> <p>19 A. Thirty-three.</p> <p>20 Q. That's two more than the 31 that you use in</p> <p>21 your report; correct?</p> <p>22 A. Okay.</p> <p>23 Q. Is that correct?</p> <p>24 A. Appears to be correct. Yeah, I used --</p> <p>25 Q. Thirty-one; correct?</p>	<p style="text-align: right;">Page 145</p> <p>1 Q. With respect to the forced-air group, there</p> <p>2 are two more infections; correct?</p> <p>3 A. There -- there are.</p> <p>4 MR. GORDON: Two more infections than he</p> <p>5 did -- he reported.</p> <p>6 A. Two more than I -- than I reported. It is</p> <p>7 one more than McGovern reported.</p> <p>8 Q. Okay.</p> <p>9 A. And the total number is --</p> <p>10 What is it?</p> <p>11 Q. One thousand --</p> <p>12 A. 1,098.</p> <p>13 Q. You mean 68?</p> <p>14 A. Thirty-two and 1066.</p> <p>15 Oh, I'm sorry, 1068 is the total.</p> <p>16 Q. Yeah.</p> <p>17 A. So this is --</p> <p>18 This says 1065 are in this report you're</p> <p>19 just showing me.</p> <p>20 Q. Uh-huh. Does this calculation give you any</p> <p>21 pause that perhaps there was more Bair Hugger</p> <p>22 infections than the amount that you've reported in</p> <p>23 your report?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>

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<p style="text-align: right;">Page 146</p> <p>1 A. Yeah. I -- I -- I don't know the sources --</p> <p>2 the sources of these data. I mean it's --</p> <p>3 There's also less -- fewer subjects.</p> <p>4 Q. The source of the data is from Mr. Albrecht;</p> <p>5 is it not?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question, lack of foundation.</p> <p>8 A. Well it's -- it's based -- I gather -- well</p> <p>9 I don't know where -- where --</p> <p>10 Where is this data? Is this part of the</p> <p>11 e -- no, this is not part of the e-mail. Where does</p> <p>12 Table 1 come from in this exhibit?</p> <p>13 Q. On the prior page Mr. Reed says, "So - for</p> <p>14 clarity - this chart is the same as the one in our</p> <p>15 paper but with longer follow up?" Correct?</p> <p>16 A. "This chart," so what is this?</p> <p>17 Q. We read that earlier.</p> <p>18 A. Is this the percent of --</p> <p>19 Results.pdf, what is it? What are we</p> <p>20 looking at?</p> <p>21 Q. We're looking at the table Mr. Reed is</p> <p>22 referring to in his e-mail.</p> <p>23 A. So this is an attachment to the e-mail, --</p> <p>24 Q. Yes.</p> <p>25 A. -- is that what you're saying?</p>	<p style="text-align: right;">Page 148</p> <p>1 software, and that was the tabulation that -- that I</p> <p>2 got using SAS.</p> <p>3 Q. And this document shows otherwise.</p> <p>4 A. This document is not showing those same</p> <p>5 results, --</p> <p>6 Q. Okay.</p> <p>7 A. -- yes.</p> <p>8 MR. SACCHET: Let's take a break.</p> <p>9 THE REPORTER: Off the record, please.</p> <p>10 (Recess taken.)</p> <p>11 (Exhibit 18 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Dr. Holford, Exhibit 18, which was</p> <p>15 previously marked as McGovern 16, is the document that</p> <p>16 you also reviewed in opining on the number of</p> <p>17 infections in the Bair Hugger study; correct?</p> <p>18 A. Yes.</p> <p>19 Q. The document is not dated; is it?</p> <p>20 A. It doesn't appear to be.</p> <p>21 Q. So you do not know when this document was</p> <p>22 finalized; correct?</p> <p>23 A. No.</p> <p>24 Q. Are you aware that Mr. McGovern never</p> <p>25 testified that this was the final data set?</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. Yes.</p> <p>2 A. Okay. So -- okay. So you're asking me</p> <p>3 about the number that developed, so they're reporting</p> <p>4 33 in this. In their -- in their paper that they</p> <p>5 published they said there were 32.</p> <p>6 Q. So it actually went up from what was</p> <p>7 published in their report.</p> <p>8 A. Went up from what was published, went up</p> <p>9 one.</p> <p>10 Q. Yeah.</p> <p>11 A. It's not the file they're looking at. The</p> <p>12 total number of cases is -- in this Table 1 goes</p> <p>13 down --</p> <p>14 Q. Uh-huh.</p> <p>15 A. -- to 1065 while here it was 10 -- 1066.</p> <p>16 Q. So why did you decide to go down instead of</p> <p>17 up?</p> <p>18 A. Why did I decide to go down --</p> <p>19 Q. You report 31 infections, this document</p> <p>20 reports 33 for forced-air warming. Why did you go</p> <p>21 down?</p> <p>22 A. Oh, because -- because I tabulated the --</p> <p>23 the file that I -- that I showed you, --</p> <p>24 Q. Okay.</p> <p>25 A. -- ran that through the statistical</p>	<p style="text-align: right;">Page 149</p> <p>1 A. I don't know what he said on it.</p> <p>2 Q. You don't know one way or another whether</p> <p>3 Mr. McGovern said this was the final data set or was</p> <p>4 not the final data set.</p> <p>5 A. No, I don't.</p> <p>6 Q. You reviewed Mr. McGovern's deposition;</p> <p>7 correct?</p> <p>8 A. I did. I just don't recall his comment</p> <p>9 on -- on -- on this particular data set.</p> <p>10 Q. In the event that Mr. McGovern made no</p> <p>11 comment regarding whether or not this was the final</p> <p>12 data set, would that impact your opinion as to whether</p> <p>13 it is or is not?</p> <p>14 A. I mean I don't -- I don't know where --</p> <p>15 I mean I'm taking -- taking the data set at</p> <p>16 face value, and he is talking about it and I --</p> <p>17 it's -- so I'm assuming it -- it --</p> <p>18 Well it formed the basis of what my -- what</p> <p>19 my opinions are. That's -- this is what I -- I based</p> <p>20 it on.</p> <p>21 Q. Well in your report you say that "The</p> <p>22 results in McGovern are incorrect because they arise</p> <p>23 from an incorrect tabulation. An error is recognized</p> <p>24 in the depositions by Albrecht, Reed and McGovern."</p> <p>25 A. That there is a --</p>

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<p style="text-align: right;">Page 150</p> <p>1 Well that's referring to not this -- not --</p> <p>2 not this exhibit, that's referring to the paper.</p> <p>3 Q. So in your --</p> <p>4 A. And so I mean an initial source of -- of --</p> <p>5 of the -- of the -- of the problem I think is -- was</p> <p>6 in Reed's testimony.</p> <p>7 Q. Okay.</p> <p>8 A. Reed testified that there was one more</p> <p>9 infection in each group.</p> <p>10 Q. We'll get there. But with respect --</p> <p>11 A. Okay.</p> <p>12 Q. -- to Mr. -- Dr. McGovern, --</p> <p>13 A. Okay.</p> <p>14 Q. -- Dr. McGovern never says anything about a</p> <p>15 tabulation error; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence.</p> <p>18 A. I don't -- I don't recall exactly what</p> <p>19 doc -- what -- all of the details of -- of McGovern.</p> <p>20 Q. So you don't know whether or not he said</p> <p>21 there was a tabulation error; correct?</p> <p>22 A. I -- I don't remember.</p> <p>23 Q. Okay. Your report says that he did</p> <p>24 recognize an error; correct?</p> <p>25 A. I may have said that.</p>	<p style="text-align: right;">Page 152</p> <p>1 exactly where -- what McGovern said, if he says it or</p> <p>2 not, but I -- but this is a big part of where -- that</p> <p>3 forms the basis for that statement.</p> <p>4 Q. But you don't know whether or not, sitting</p> <p>5 here today, Mr. McGovern -- Dr. McGovern said that</p> <p>6 there was a tabulation error or there was not a</p> <p>7 tabulation error.</p> <p>8 A. I don't recall --</p> <p>9 Q. Okay.</p> <p>10 A. -- this morning.</p> <p>11 Q. If we could go back to the previous marked</p> <p>12 document which is McGovern Exhibit 16 --</p> <p>13 A. To which document?</p> <p>14 Q. Exhibit 18 I believe.</p> <p>15 A. Okay.</p> <p>16 MR. GORDON: Eighteen? What -- what -- just</p> <p>17 what is it?</p> <p>18 THE WITNESS: McGovern 16 --</p> <p>19 MR. SACCHET: McGovern 16 --</p> <p>20 THE WITNESS: -- which is 18.</p> <p>21 MR. SACCHET: -- which is 18.</p> <p>22 THE WITNESS: Yeah, okay.</p> <p>23 MR. GORDON: Oh.</p> <p>24 Q. Did you review any other data sets that were</p> <p>25 produced by Dr. McGovern?</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. Pages two and three. I don't want to spend</p> <p>2 a ton of time on this, but --</p> <p>3 A. I mean there's --</p> <p>4 Q. -- the quote is --</p> <p>5 A. I -- I -- I --</p> <p>6 Q. Can I read you the quote?</p> <p>7 A. Yes.</p> <p>8 Q. "The results by McGovern are incorrect,</p> <p>9 however, because they arise from an incorrect</p> <p>10 tabulation. An error is recognized in the depositions</p> <p>11 by Albrecht, Reed and McGovern."</p> <p>12 A. Okay. The tabulation, based on this, if you</p> <p>13 look at -- count the numbers in here, I think they</p> <p>14 agree with -- with my tabulation --</p> <p>15 Q. Okay.</p> <p>16 A. -- in -- in terms of the numbers and the</p> <p>17 dates in which these -- these occur, and so that's</p> <p>18 based on this -- this table --</p> <p>19 Q. So you --</p> <p>20 A. -- of data.</p> <p>21 Q. You're relying on the table, not Mr.</p> <p>22 McGovern's testimony -- Dr. McGovern's testimony.</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question.</p> <p>25 A. I -- I -- I -- as I say, I don't recall</p>	<p style="text-align: right;">Page 153</p> <p>1 A. I don't recall --</p> <p>2 That were produced by him, no.</p> <p>3 Q. If he had produced other data sets, how do</p> <p>4 you know that this is the data set that includes the</p> <p>5 data that was published in the McGovern study?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question, assumes facts not in evidence.</p> <p>8 A. I -- I mean the whole -- the whole past of</p> <p>9 where these files came from is -- is not something</p> <p>10 that I saw.</p> <p>11 Q. You don't know where they came from.</p> <p>12 A. Well I -- I know who gave them to me.</p> <p>13 Q. Who gave them to you?</p> <p>14 A. 3M.</p> <p>15 Q. But you don't know who produced these.</p> <p>16 A. No.</p> <p>17 Q. Okay. If we turn to the very last page of</p> <p>18 this document, Exhibit 18, --</p> <p>19 A. Okay.</p> <p>20 Q. -- there is a condensed table, correct, with</p> <p>21 various fields summing through --</p> <p>22 Very last. The last page with a table on</p> <p>23 it. I think you're looking at the first --</p> <p>24 A. In my page it's Table 1.</p> <p>25 Q. The front of the document has this stamp on</p>

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<p style="text-align: right;">Page 154</p> <p>1 it, doctor, so that's the first page. 2 A. Oh, I see. 3 Q. Yeah. First -- 4 It was marked, actually, on the reverse 5 side -- 6 A. Okay. 7 Q. -- so that's where the confusion is. 8 If you turn to the last page, which is 9 actually, from what I can see on your document, the 10 one with the blue sticker on it -- 11 A. That's the one I was looking at. 12 Q. Yeah. 13 A. Okay. Sorry. 14 Q. -- there are a number of fields here. I 15 recognize it's small and I apologize for that. 16 However, you reviewed this table; correct? 17 A. Yes. 18 Q. And column BJ is the date-of-surgery column; 19 correct? 20 A. Yes. 21 Q. Okay. 22 A. Appears to be, yeah. 23 Q. And in your report you single out row 44, 24 which has a date of surgery of 9/15/2007 -- 25 A. Yes.</p>	<p style="text-align: right;">Page 156</p> <p>1 My tabulation was based on the date that was 2 given. 3 Q. It was not based on the device coding. 4 A. Not the -- 5 No. 6 Q. And if you could -- 7 We're going to toggle back between two 8 different documents, so -- 9 A. Okay. 10 Q. I don't want you to get too mixed up here, 11 but if you can go back to the McGovern study which we 12 had marked as Exhibit 13 in this deposition -- 13 A. Okay. 14 Q. -- and pull that out. 15 A. Okay. 16 Q. And I just want you to hold Fig. 7, which is 17 in the back end of the McGovern study, next to the 18 table in front of you. So you can just pull up Fig. 19 7 in the McGovern study. 20 MR. GORDON: And what is -- 21 What are we holding it next to? 22 Q. Just simply if you can pull up Fig. 7 and 23 put it down and have the table that we just marked 24 from McGovern Exhibit 16 next to it. 25 Yup, you got it. Okay. Yeah. And let's --</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. -- and as coded as FAW; correct? 2 MR. GORDON: 2010. 3 MR. SACCHET: Oh, I'm sorry. Thank you, Mr. 4 Gordon. 5 Q. -- 9/15/2010 and as coded as forced-air 6 warming; correct? 7 A. That's correct. 8 Q. Okay. How do you know that it was 9 incorrectly coded as to the type of device instead of 10 the type of -- date? 11 A. I don't know that. 12 Q. But you're relying on the fact that this 13 surgery in fact occurred on September 15th, 2010; 14 correct? 15 A. That's right. 16 I mean if -- if the date is wrong and that 17 date should be, you know, sometime during the Bair 18 Hugger period, then not only the numerator would be 19 wrong but the denominator would be wrong as well. I 20 think the total number of cases is -- in my tabulation 21 is the same as, I believe -- 22 Let me double check that. So 4037 -- 23 No. I'm sorry. Yeah, I'm -- I'm assuming 24 that -- that that is -- that -- that the date is 25 correctly -- it was based --</p>	<p style="text-align: right;">Page 157</p> <p>1 You have to hold them there. 2 A. Okay. 3 Q. I recognize that this is a hypothetical, but 4 in the event that row 44 in this table, -- 5 A. Uh-huh. 6 Q. -- if that infection had actually occurred 7 in September of 2008, that would be in the Bair Hugger 8 period; correct? 9 A. Yes. Yeah. 10 Q. Okay. Have you ever created a graph like 11 Fig. 7 before? 12 MR. GORDON: Object to the form of the 13 question. 14 A. No. 15 Q. Okay. But you understand that the X axis is 16 a range of dates and the Y axis is the percent of 17 infection; correct? 18 A. Well it -- it depends on which axis you're 19 looking at. It's the number -- it's -- there's a -- 20 There is a left and a right axis. 21 Q. Okay. The horizontal line on the bottom of 22 the graph goes from July 2008 to January 2011; right? 23 A. Yes. 24 Q. Okay. And there's a number of data points 25 in this graph and some are on the top and some are on</p>

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<p style="text-align: right;">Page 158</p> <p>1 the bottom; correct?</p> <p>2 A. Yeah.</p> <p>3 Q. And based on the axis on the right-hand</p> <p>4 side, those on the bottom designate no infection and</p> <p>5 those on the top designate infection; correct?</p> <p>6 A. Correct.</p> <p>7 Q. And the legend for Fig. 7 notes that the</p> <p>8 data points have been jittered to avoid overprinting;</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. And my understanding of that is essentially</p> <p>12 that when you look at the graph, there could be two</p> <p>13 data points that have similar times, but you don't put</p> <p>14 them on top of each other because it would just look</p> <p>15 like one point; is that correct?</p> <p>16 A. That's right. They're trying to see it. I</p> <p>17 mean in the Xerox you kind of lose it, but --</p> <p>18 Q. Okay.</p> <p>19 A. Yeah. Yeah.</p> <p>20 Q. And if you were to attempt to re-create this</p> <p>21 graph --</p> <p>22 A. Uh-huh?</p> <p>23 Q. -- in a similar way that you recalculated</p> <p>24 the data in the study, because each jittered data</p> <p>25 point is specific to a date, --</p>	<p style="text-align: right;">Page 160</p> <p>1 THE REPORTER: Your answer? Your answer?</p> <p>2 THE WITNESS: Yes.</p> <p>3 Q. Okay. Have you compared this graph to</p> <p>4 Exhibit 18 in this case but was previously marked as</p> <p>5 Exhibit 16 by McGovern in -- in the McGovern</p> <p>6 deposition, have you done this side-by-side comparison</p> <p>7 before?</p> <p>8 A. No.</p> <p>9 Q. Okay. So I'm going to walk you through this</p> <p>10 and I'll do my best to do it slowly, but the first</p> <p>11 infection data point that we have in Fig. 7 of the</p> <p>12 McGovern study appears to be July 2008; correct?</p> <p>13 Right on the beginning of the study period in the</p> <p>14 graph of Fig. 7, the first data point in the infection</p> <p>15 area.</p> <p>16 A. First infection. I guess so.</p> <p>17 Q. Yeah. And if you go to McGovern 16, the</p> <p>18 first infection, which is row six, the date of surgery</p> <p>19 is July 1st, 2008; correct?</p> <p>20 A. That's right.</p> <p>21 Q. So that data point matches this date in</p> <p>22 McGovern 16; correct?</p> <p>23 A. Okay.</p> <p>24 Q. Do you agree?</p> <p>25 A. Yeah, it seems to be.</p>
<p style="text-align: right;">Page 159</p> <p>1 A. Yes.</p> <p>2 Q. -- that's the manner in which you would have</p> <p>3 to represent it on the graph; correct?</p> <p>4 A. My -- my assumption is -- is the jitter has</p> <p>5 to do with the vertical jitter. They vertically</p> <p>6 jittered it and not -- so the -- so the date --</p> <p>7 It appears on the right date, --</p> <p>8 Q. Yup.</p> <p>9 A. -- it's just the no-infection point is sort</p> <p>10 of -- and they jittered both the no infections and the</p> <p>11 infections. If you notice, they're not all exactly</p> <p>12 the same points, so they --</p> <p>13 Q. Well let me put it this way: If you were</p> <p>14 going to put these dots on this graph, --</p> <p>15 A. Yeah.</p> <p>16 Q. -- you wouldn't be able to put them in the</p> <p>17 right location if you were just saying is it infection</p> <p>18 or is it non-infection; right? You need to consider</p> <p>19 the date of the infection or non-infection; right?</p> <p>20 A. Yeah, it's -- it's by the date, yeah.</p> <p>21 Q. So the date is the way in which you</p> <p>22 determine where each infection or non-infection goes</p> <p>23 on the graph.</p> <p>24 A. Uh-huh.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Yeah. Okay.</p> <p>2 A. Yeah.</p> <p>3 Q. Now looking at the table, the next three</p> <p>4 infections are August 7, 2008, August 12, 2008 and</p> <p>5 August 13, 2008; correct?</p> <p>6 A. Yes.</p> <p>7 Q. In McGovern 16 --</p> <p>8 Which we've marked as Exhibit 18; correct?</p> <p>9 A. Right.</p> <p>10 Q. -- do you see the cluster of three jittered</p> <p>11 data points in the infection area of this graph?</p> <p>12 A. Yes.</p> <p>13 Q. That appears to align with those three</p> <p>14 infections; correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. The next cell in McGovern 16 is</p> <p>17 September 30th, 2008; correct?</p> <p>18 A. Yeah.</p> <p>19 Q. And the infection after that is November</p> <p>20 4th, 2008; correct?</p> <p>21 In the cell.</p> <p>22 A. Yeah.</p> <p>23 Q. Okay. So that's a gap of about a month and</p> <p>24 five days, September --</p> <p>25 A. Yeah.</p>

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<p style="text-align: right;">Page 162</p> <p>1 Q. -- 30th to November 4th; correct?</p> <p>2 A. It is, yeah.</p> <p>3 Q. Okay. Now let's go to the graph. There are</p> <p>4 two points in a horizontal line virtually on top of</p> <p>5 each other; correct?</p> <p>6 A. Yeah.</p> <p>7 Q. One of those points must be the September</p> <p>8 30th data point; correct? Because that's the next</p> <p>9 infection in the table and that's the next infection</p> <p>10 reported in the graph.</p> <p>11 A. It could be. I mean it's -- now you're</p> <p>12 sort of --</p> <p>13 Q. Well I mean it --</p> <p>14 A. It's hard to tell. The -- the axis is so</p> <p>15 rough it's a little hard to tell exactly, but it seems</p> <p>16 plausible.</p> <p>17 Q. I mean if the prior three infections are the</p> <p>18 cluster of three, which are all August infections, --</p> <p>19 A. Yeah.</p> <p>20 Q. -- the next data point must be September,</p> <p>21 correct, and that's the next infection in the McGovern</p> <p>22 16 Excel file.</p> <p>23 A. It could be, yeah.</p> <p>24 Q. You're saying that McGovern 16 is the final</p> <p>25 data set; correct?</p>	<p style="text-align: right;">Page 164</p> <p>1 to look at it.</p> <p>2 MR. SACCHET: I'm not -- I'm not there right</p> <p>3 now, but I appreciate it, Mr. Gordon.</p> <p>4 MR. GORDON: But in fairness, there are no</p> <p>5 infections listed on that.</p> <p>6 MR. SACCHET: I appreciate your testimony.</p> <p>7 MR. GORDON: Well it stands in contrast to</p> <p>8 you giving him an exhibit missing a page and implying</p> <p>9 that there was something on that page that maybe, you</p> <p>10 know, was a September 15th, 2008 --</p> <p>11 MR. SACCHET: I'm talking about McGovern 16</p> <p>12 right now.</p> <p>13 MR. GORDON: I -- I was --</p> <p>14 No, you were talking about --</p> <p>15 MR. SACCHET: I wasn't talking at all about</p> <p>16 this.</p> <p>17 MR. GORDON: But -- but you set this whole</p> <p>18 thing up with a missing page --</p> <p>19 MR. SACCHET: That's how it was produced.</p> <p>20 MR. GORDON: I don't know if that was how it</p> <p>21 was produced or not.</p> <p>22 MR. SACCHET: Ask DFT.</p> <p>23 MR. GORDON: Pardon?</p> <p>24 MR. SACCHET: Ask DFT if that's the final</p> <p>25 copy.</p>
<p style="text-align: right;">Page 163</p> <p>1 A. I didn't say that. I --</p> <p>2 Q. So you don't know that McGovern 16 is the</p> <p>3 final data set.</p> <p>4 A. No, I don't.</p> <p>5 Q. Okay.</p> <p>6 A. But I mean it seems plausible.</p> <p>7 MR. GORDON: Counsel, counsel --</p> <p>8 A. It's hard to sort of compare here because</p> <p>9 this axis is -- you know, the cut points are --</p> <p>10 Q. Yeah.</p> <p>11 A. -- six months --</p> <p>12 Q. I understand. I just wanted to clarify</p> <p>13 that.</p> <p>14 A. Yeah.</p> <p>15 MR. GORDON: Counsel, I just want -- want to</p> <p>16 let you know I have e-mailed to you and Ms. Conlin the</p> <p>17 Augustine Bates number 0005277 --</p> <p>18 MR. SACCHET: I know.</p> <p>19 MR. GORDON: -- that seems to have been</p> <p>20 missing in the copy which you -- you marked as Exhibit</p> <p>21 14.</p> <p>22 MR. SACCHET: Okay.</p> <p>23 MR. GORDON: I don't know if it's a</p> <p>24 photocopy error or whatever, but anyway, you do have</p> <p>25 access to it. I can call it up on my iPad if you want</p>	<p style="text-align: right;">Page 165</p> <p>1 MR. GORDON: Well then maybe DFT screwed up.</p> <p>2 I don't know. But you now have --</p> <p>3 MR. SACCHET: Thank you.</p> <p>4 MR. GORDON: -- 5277 --</p> <p>5 MR. SACCHET: Great.</p> <p>6 MR. GORDON: -- in your e-mail and it shows</p> <p>7 no infection.</p> <p>8 MR. SACCHET: I'll note for the record the</p> <p>9 two-minute soliloquy by Mr. Gordon as a speaking</p> <p>10 objection that should be not raised in any deposition</p> <p>11 of an expert witness in this litigation.</p> <p>12 Q. Back to McGovern 16 -- which is actually the</p> <p>13 document that we were speaking about, not Albrecht</p> <p>14 Exhibit 10 -- you stated you don't know whether</p> <p>15 McGovern 16 is the final data set, but I want to draw</p> <p>16 your attention back to the graph, and there are two</p> <p>17 dots there; correct?</p> <p>18 A. Right.</p> <p>19 Q. And they're on top of each other; correct?</p> <p>20 A. Yes.</p> <p>21 Q. And if the infection cell in the McGovern</p> <p>22 table was from 9/30/2009 and that's the next</p> <p>23 infection, the second data point in the graph should</p> <p>24 be from a similar time period; correct?</p> <p>25 A. So where are you now?</p>

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<p style="text-align: right;">Page 166</p> <p>1 Q. Okay. So I'm still on the one we were 2 talking about, before I was interrupted about a 3 different exhibit, which is row 10 with the September 4 30th, 2008 infection. Do you see that? 5 A. Right. Uh-huh. 6 Q. Okay. And the next infection isn't until 7 November 4th, 2008; correct? 8 A. That's right. 9 Q. And that's about a month-long gap; right? 10 A. Right. 11 Q. But in the graph we have two dots -- 12 A. Yeah. 13 Q. -- right on top of each other, one of which 14 you said is plausibly the September 30th, 2008 15 infection; correct? 16 A. Septem -- 17 You're -- you're -- you're talking about 18 number 10? 19 Q. Yup. It's September 30th, 2008; correct? 20 A. It's September 30. Okay. 21 Q. Okay. 22 A. So that's one of the -- 23 Q. That's one of those two. 24 A. -- two. 25 Q. Yeah.</p>	<p style="text-align: right;">Page 168</p> <p>1 the cluster of three on the left that's paired with 2 the September 30th, 2008 infection? 3 A. I don't know. 4 MR. GORDON: Object to the form of the 5 question. 6 Q. It's not in the McGovern 16 table; is it? 7 MR. GORDON: Lack of foundation. 8 A. I -- I don't know what formed this graph. I 9 don't -- I mean -- 10 Q. This is the graph that's reported in the 11 published study; correct? 12 A. It is a graph in the -- in the published 13 study, -- 14 Q. Yeah. I mean -- 15 A. -- but the data that went -- that formed 16 this graph I do not -- I don't know that I've seen. 17 It doesn't seem to be this table. 18 Q. Yeah. So it's -- this -- 19 This jittered data point is not in McGovern 20 16. 21 A. It doesn't appear to be. 22 Q. And this jit -- jittered data point is in 23 2008. 24 A. It -- 25 Yeah, it does seem to be in 2008.</p>
<p style="text-align: right;">Page 167</p> <p>1 A. Okay. 2 Q. And the next infection is not until November 3 4th -- 4 A. Yeah. 5 Q. -- in McGovern 16; correct? 6 A. Right. 7 Q. And the one after that's November 7th -- 8 A. Yeah. 9 Q. -- and the one after that's November 18th; 10 right? 11 A. Right. 12 Q. Do you see the cluster of three data 13 points -- 14 A. Yeah. 15 Q. -- after the two? 16 A. Yes. 17 Q. Those are presumably the November cluster of 18 infections; correct? 19 MR. GORDON: Object to the form of the 20 question, lack of foundation. 21 A. I don't know for sure. It -- 22 Q. It appears to be. 23 A. It's plausible. 24 Q. Okay. What is the second date -- the second 25 dot in between the cluster of three on the right and</p>	<p style="text-align: right;">Page 169</p> <p>1 Q. That's during the Bair Hugger warming 2 period; correct? 3 A. Uh-huh. 4 Q. So there appears to be an additional 5 jittered data point in the 2008 Bair Hugger period 6 that is not reflected on the McGovern 16 -- 7 A. Yeah. Yeah. 8 Q. -- file. 9 A. Yeah. 10 MR. GORDON: Object to the form of the 11 question, lack of foundation. 12 Q. And if you take away cell 44 for the sake of 13 argument and you add in the data point that we just 14 discussed, which is in the Bair Hugger period from 15 2008, that gives you 32 infections. 16 MR. GORDON: Object to the form of the 17 question, lack of foundation, in -- incomplete 18 hypothetical. 19 A. So I don't under -- 20 Q. I can break it down further if you want. 21 A. Yeah. What exactly are you proposing? 22 Q. Okay. So in your report you say cell 44 was 23 miscoded to be -- 24 A. Yeah. 25 Q. -- a forced-air warming infection because</p>

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<p style="text-align: right;">Page 170</p> <p>1 the date of infection -- or date of operation was 2 September 15, 2010; right? 3 A. Yes. 4 Q. So if we just take that off the table, we're 5 down to the 31 infections that you assume in your 6 report; correct? 7 A. Yes. 8 Q. Okay. And this jittered data point in 2008 9 is not reflected in McGovern 16. That's what you just 10 testified to. 11 A. It doesn't seem to be. 12 Q. Okay. If we add that data point into this 13 graph, there are 32 infections. 14 A. Okay. Yes. 15 Q. Thank you. 16 MR. SACCHET: We'll take a break. 17 THE REPORTER: Off the record, please. 18 (Luncheon recess taken.) 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 172</p> <p>1 A. That's correct. 2 Q. Do you have any reason for not relying on 3 Dr. Reed's recollection of one additional infection in 4 each arm versus the Albrecht Exhibit 10 and McGovern 5 Exhibit 16? 6 A. No. I was just taking what -- 7 You know, it's just based on what he said -- 8 Q. You would agree that -- 9 A. -- in his deposition. 10 Q. Are you finished? 11 A. Yes. 12 Q. You would agree that the calculations that 13 you have performed that are within your report rely on 14 McGovern 16 and Albrecht Exhibit 10; correct? 15 A. I think all of the rest of the calculations, 16 other than footnote one, are based on 10 and 16. 17 Q. And you recognize that Mr. Reed's testimony 18 and the cal -- and the calculation you performed based 19 on that testimony has a higher odds ratio of 2.86 than 20 the 2.76 that you used throughout the report, which 21 are based on Albrecht 10 and McGovern 16. 22 A. That's right. 23 Q. So it's possible that in fact the OR of 2.86 24 could be the actual odds ratio of the study. 25 A. Yes. There seems to be some error in the</p>
<p style="text-align: right;">Page 171</p> <p>1 AFTERNOON SESSION 2 BY MR. SACCHET: 3 Q. Dr. Holford, I should ask, do you prefer 4 going by doctor or professor? 5 A. Professor is fine. Either one. 6 Q. Okay. In your report on page two you also 7 reference the testimony of Dr. Reed; correct? 8 A. Yes. 9 Q. And you state that the published McGovern 10 analysis may have been in error in light of that 11 testimony; correct? 12 A. Yes. 13 Q. And that testimony suggested that there may 14 have been an additional infection both in the Bair 15 Hugger arm and in the Hot Dog arm; correct? 16 A. That's correct. 17 Q. And you also perform a calculation in 18 footnote one of your report that states, "Even if one 19 assumes that Dr. Reed's recollection in his deposition 20 was correct (that there was one additional infection 21 in each group), the odds ratio is nevertheless 22 markedly different than reported in the published 23 paper," and you go on to note that the odds ratio 24 would be 2.86 with a significant p-value of .0356; 25 correct?</p>	<p style="text-align: right;">Page 173</p> <p>1 tabulation in the -- in the paper is what -- what 2 seems to be implied by this testimony of, you know, 3 Reed and Albright and -- and whatever, so I'm trying 4 to sort out as best I can what that error is. 5 Q. And you would agree that the calculation you 6 performed as to Mr. Reed's testimony contradicts the 7 calculation you performed with respect to the McGovern 8 Exhibit 16 and Albrecht Exhibit 10 data; correct? 9 A. It -- it is different, yes. 10 Q. And the Reed calculation results in a 11 significant p-value; correct? 12 A. That's right. 13 Q. To be specific, the calculation on page two 14 of your report where you derive a p-value -- or an 15 odds ratio of 2.76 derives from McGovern Exhibit 16 16 and Albrecht Exhibit 10; correct? 17 A. That's correct. 18 Q. To also be clear, the time trend data which 19 you discuss on page four of your report also derives 20 from Albrecht Exhibit 10 and McGovern Exhibit 16; 21 correct? 22 A. That's correct. 23 Q. The reanalysis of the Jensen data that you 24 performed on page five of your report also depends on 25 the veracity of McGovern Exhibit 16 and Albrecht</p>

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<p style="text-align: right;">Page 174</p> <p>1 Exhibit 10. 2 A. That's correct. 3 Q. The calculation you performed on page four 4 with respect to controlling for the thromboprophylaxis 5 also derives from Albrecht Exhibit 10 and McGovern 6 Exhibit 16; correct? 7 A. Correct. 8 MR. GORDON: Object to the form of the 9 question. 10 Q. The calculation you performed also on page 11 six with respect to controlling for the antibiotic 12 derives from the data in McGovern Exhibit 16 and 13 Albrecht Exhibit 10; correct? 14 A. Yes. 15 Q. And finally, with respect to the conclusions 16 that you offer in terms of causal inferences in the 17 latter parts of your report, those calculations so too 18 rely on the data from McGovern Exhibit 16 and Albrecht 19 Exhibit 10; correct? 20 A. Yes. They're basically referring to the 21 analyses I did in the previous sections. 22 Q. So all those calculations depend on the 23 veracity of Albrecht Exhibit 10 and McGovern Exhibit 24 16. 25 A. Yes, I think that's right. Yeah.</p>	<p style="text-align: right;">Page 176</p> <p>1 A. Yes, I did. 2 Q. And when you perform that calculation, you 3 also find a significant p-value; correct? 4 A. That's correct. 5 Q. And the p-value with respect to the reported 6 data using Fisher's is .0176; correct? 7 A. That's correct. Yeah. 8 Q. So I've been trying to figure this out 9 because I know that Fisher's exact is generally a more 10 conservative test, but in this particular instance 11 chi-squared had a less significant p-value but which 12 was still significant than under Fisher. Is that -- 13 And I can back up. The p-value using X 14 chi-squared was .024 in the study; correct? 15 A. That's right. 16 Q. And then when you did Fisher's on the -- the 17 data reported in this study, you got a p-value of 18 .07 -- .0176. 19 A. Yeah. 20 Q. So in that particular instance the p-value 21 actually increased by using chi-squared; correct? 22 A. It -- it did. The Fisher's -- but I -- 23 The premise I think of your question was 24 that Fisher's is conservative. 25 Q. And we can get to that later.</p>
<p style="text-align: right;">Page 175</p> <p>1 Q. I'm going to change gears a little bit now 2 and talk about the particular tests that -- 3 statistical tests that were used both in the McGovern 4 study and in your report. 5 A. Uh-huh. 6 Q. With respect to -- with respect to reviewing 7 the McGovern study, the authors used chi-squared; 8 correct? 9 A. That's correct. 10 Q. And their calculation, when using the data 11 reported in this study, resulted in a p-value of .024; 12 correct? 13 A. I think that's correct. That sounds -- 14 sounds right. I'd have to look back at the paper, but 15 I think it's right. 16 Q. Okay. It is, but -- 17 And based on the chi-squared on that data 18 set, the odds ratio is 3.8. 19 A. That's right. 20 Q. And the confidence interval was 1.2 to 12.5; 21 correct? 22 A. That's right. 23 Q. Now in your report you also apply Fisher's 24 exact test to the data that was reported in the 25 McGovern study; correct?</p>	<p style="text-align: right;">Page 177</p> <p>1 A. Oh, okay. I would disagree with that -- 2 Q. Okay. 3 A. -- characterization. 4 Q. But with respect to what we're talking about 5 now, the p-val -- p-value actually went down when 6 using Fisher's as opposed to chi-squared. 7 A. That's correct. 8 Q. If the authors had truly wanted to cherry 9 pick a p-value, they could have employed Fisher's and 10 had a more significant p-value; correct? 11 A. They -- they could have, yes. 12 Q. And they did not. 13 A. No. 14 Q. When using Fisher's on the original data set 15 reported in the McGovern study, the OR, instead of 16 being 3.8, is 3.79, correct, so virtually identical? 17 A. Yeah, uh-huh. I assume it just depends on 18 how much -- 19 What you're rounding is I think the 20 difference. 21 Q. Okay. Now going back to the data that you 22 used in your report; namely, the four infections in 23 the Hot Dog period and the 31 infections in the Bair 24 Hugger period, -- 25 A. Uh-huh.</p>

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<p style="text-align: right;">Page 178</p> <p>1 Q. -- you also used that data and calculated</p> <p>2 p-values and odds ratios using chi-squared; correct?</p> <p>3 A. For the analysis on --</p> <p>4 Let's see, where is it?</p> <p>5 Q. Page two.</p> <p>6 A. Page two. I mean the p-value I give there</p> <p>7 is -- is actually the F -- I'm sorry, Fisher's --</p> <p>8 Fisher's exact.</p> <p>9 Q. Did you report a p-value of .0480 when using</p> <p>10 chi-squared --</p> <p>11 A. Oh, I'm sorry.</p> <p>12 Q. -- on the remixed data set?</p> <p>13 A. That's true. I also -- I also did the</p> <p>14 chi-square in the --</p> <p>15 Yeah, it got a little lower.</p> <p>16 Q. And you note that it is just below the</p> <p>17 threshold of statistical significance; correct?</p> <p>18 A. That's right.</p> <p>19 Q. It's the same p-value that was reported in</p> <p>20 the Jensen study which you cited in your reference</p> <p>21 material; correct?</p> <p>22 MR. GORDON: Which -- which is?</p> <p>23 THE WITNESS: Which --</p> <p>24 MR. SACCHET: The Jensen study on control --</p> <p>25 MR. GORDON: No, which -- which of the</p>	<p style="text-align: right;">Page 180</p> <p>1 question was that they reported a statistically</p> <p>2 significant difference in infection rates at that</p> <p>3 p-value, that's -- and that's not what they did.</p> <p>4 Q. I'll rephrase my question.</p> <p>5 A. They didn't -- yeah.</p> <p>6 Q. I'll rephrase the question.</p> <p>7 Is the p-value that's reported in the</p> <p>8 abstract of the Jensen study 0.048?</p> <p>9 I recognize that the 8 is difficult to read.</p> <p>10 A. It's hard to see if it's an 8 or a 6, but</p> <p>11 yeah, it's -- it's less than .05.</p> <p>12 Q. Okay. And the authors there deemed it to be</p> <p>13 statistically significant.</p> <p>14 MR. GORDON: What --</p> <p>15 A. That's right.</p> <p>16 Q. They made no mention that it was marginally</p> <p>17 significant or close to the threshold of significance.</p> <p>18 A. They didn't say.</p> <p>19 Q. So whether or not one uses the original data</p> <p>20 as reported in the McGovern study or the reanalyzed</p> <p>21 data that you provide in your report, --</p> <p>22 A. Uh-huh?</p> <p>23 Q. -- using X-squared results in a significant</p> <p>24 p-value; correct? Under .05.</p> <p>25 A. That's right, yeah.</p>
<p style="text-align: right;">Page 179</p> <p>1 p-values, the chi-square one or the --</p> <p>2 Q. The chi-squared P&L value of .0480 --</p> <p>3 A. Okay.</p> <p>4 Q. -- is the same p-value that Jensen et al</p> <p>5 reported in their study, which evaluated whether there</p> <p>6 was an increased risk of infection between using</p> <p>7 Xarelto versus using a low-molecular-weight heparin.</p> <p>8 A. I don't remember what they -- exactly what</p> <p>9 they reported.</p> <p>10 (Exhibit 19 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. SACCHET:</p> <p>13 Q. Exhibit 19 is entitled "Return to theatre</p> <p>14 following total hip and knee replacement, before and</p> <p>15 after the introduction of rivaroxaban," by Jensen et</p> <p>16 al; correct?</p> <p>17 A. Yes. And where are you --</p> <p>18 Q. In the abstract on the first page in the</p> <p>19 second paragraph, the statement there says, "Nine</p> <p>20 patients in the control (tinzaparin) group returned to</p> <p>21 theatre with wound complications within 30 days,</p> <p>22 compared with 22 patients in the rivaroxaban group.</p> <p>23 This increase was statistically significant (at p</p> <p>24 equals 0.048)."</p> <p>25 MR. GORDON: Counsel, I think your earlier</p>	<p style="text-align: right;">Page 181</p> <p>1 Q. You go on in your report, however, to state</p> <p>2 that Fisher's exact test is the more appropriate test</p> <p>3 in this circumstance; correct, professor?</p> <p>4 A. Uh-huh.</p> <p>5 THE REPORTER: Your answer?</p> <p>6 THE WITNESS: Yes. Yeah.</p> <p>7 Q. Notwithstanding your view as to the</p> <p>8 proprietary of Fisher's versus chi-squared, you'd</p> <p>9 agree that there is a long-standing debate about</p> <p>10 whether to use Fisher's or chi-squared based on</p> <p>11 certain determinants such as sample size and incidence</p> <p>12 of an outcome; correct?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question.</p> <p>15 A. I -- I don't know that there's a debate. I</p> <p>16 think it's -- Fisher's is -- is --</p> <p>17 I mean chi-square de -- derives from a -- a</p> <p>18 mathematical approximation for what the distribution</p> <p>19 is for the statistic that you're looking at, and so</p> <p>20 it's relying on that approximation. The approximation</p> <p>21 works quite well if the sample size is large, it works</p> <p>22 more poorly as the -- as the expected number of cases</p> <p>23 becomes smaller and smaller. And so it -- it's in --</p> <p>24 In contrast, the Fisher's exact test is not</p> <p>25 an approximation, it's an exact calculation.</p>

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<p style="text-align: right;">Page 182</p> <p>1 That's -- so because -- depending on the --</p> <p>2 You know, if results that go into that</p> <p>3 are -- are appropriate, then you're getting a -- an</p> <p>4 actual p-value and not an approximate p-value, which</p> <p>5 is what the chi-square is -- chi-square is yielding,</p> <p>6 so in that respect I don't know that there's a huge</p> <p>7 debate or controversy about that. The only --</p> <p>8 Chi-square is a lot easier to compute, and</p> <p>9 so when you're doing it by hand it's a lot more work</p> <p>10 to do Fisher's, but if you're just typing in the table</p> <p>11 into a -- into a computer, which of course is what we</p> <p>12 have now, it's pretty straightforward to do.</p> <p>13 Q. But you're aware that other statisticians</p> <p>14 have criticized Fisher's exact test as being overly</p> <p>15 conservative; are you not?</p> <p>16 A. I'm not sure it's particularly overly --</p> <p>17 overly conservative.</p> <p>18 Q. Not in your view. I'm saying are you --</p> <p>19 A. Yes.</p> <p>20 Q. -- aware of other statisticians who have</p> <p>21 criticized Fisher's exact test as being overly</p> <p>22 conservative?</p> <p>23 A. Some might argue that, yeah.</p> <p>24 Q. So there is a --</p> <p>25 A. It -- it's not -- but it's not uniformly --</p>	<p style="text-align: right;">Page 184</p> <p>1 Statistician in 1976?</p> <p>2 A. Ooh, I don't know. I may have at some</p> <p>3 point. I don't remember.</p> <p>4 Q. So you're not aware one way or the other</p> <p>5 whether Professor Liddell said Fisher's exact test was</p> <p>6 overly conservatively in that article.</p> <p>7 A. He may well have. I'm not -- just -- I just</p> <p>8 don't recall that paper off the top of my head.</p> <p>9 Q. He's an expert in the field; correct?</p> <p>10 A. Yeah, uh-huh.</p> <p>11 Q. I assume you're also aware of Professor --</p> <p>12 or Dr. Joseph Berkson from the Mayo Clinic in</p> <p>13 Minneapolis.</p> <p>14 A. Yes.</p> <p>15 Q. He was the head of biometry at the Mayo</p> <p>16 Clinic?</p> <p>17 A. Yes.</p> <p>18 Q. Same field as you; right?</p> <p>19 A. That's right.</p> <p>20 Q. And the Mayo Clinic is a well-respected</p> <p>21 institution; correct?</p> <p>22 A. Yes.</p> <p>23 Q. You respect Professor Berkson's views?</p> <p>24 A. Basically, yeah. I mean, yeah, he was there</p> <p>25 a while ago.</p>
<p style="text-align: right;">Page 183</p> <p>1 the --</p> <p>2 The direction does not go one way. I mean</p> <p>3 as you -- as you --</p> <p>4 Q. Yeah.</p> <p>5 A. -- just pointed out, --</p> <p>6 Q. It can go down.</p> <p>7 A. -- Fisher's can -- can be greater or less,</p> <p>8 and the context in which I used Fisher's is that I</p> <p>9 think it's more accurate when the numbers are small</p> <p>10 and -- as in these tables.</p> <p>11 Q. I'll get to that in a moment. I just want</p> <p>12 to pin down --</p> <p>13 A. Sure.</p> <p>14 Q. -- that there are statisticians who have</p> <p>15 criticized Fisher's exact test as being overly</p> <p>16 conservative.</p> <p>17 A. Okay.</p> <p>18 Q. You agree.</p> <p>19 A. There may be a few that -- that don't agree,</p> <p>20 but --</p> <p>21 Q. Do you know Professor Douglas Liddell of</p> <p>22 McGill University?</p> <p>23 A. I know of him, yeah.</p> <p>24 Q. Have you read "Practical Tests of 2 x 2</p> <p>25 Contingency Tables" that was published in The</p>	<p style="text-align: right;">Page 185</p> <p>1 Q. Have you read his article and his praises of</p> <p>2 the exact test?</p> <p>3 A. I -- I may have. I don't remember. When</p> <p>4 was that published?</p> <p>5 Q. I actually don't know when it was published.</p> <p>6 I think it was in the '80s.</p> <p>7 A. Okay.</p> <p>8 Q. But are you aware of his conclusion that the</p> <p>9 use of the term "Fisher's exact" is simply just a</p> <p>10 sobriquet because it derives from R. A. Fisher's</p> <p>11 creation of the test?</p> <p>12 A. That's -- that's a --</p> <p>13 Yeah. Fisher I know derived the test and --</p> <p>14 Q. But the use of the word "exact" really -- I</p> <p>15 mean is a sobriquet.</p> <p>16 A. Well the --</p> <p>17 I suppose. I mean it's exact if -- if --</p> <p>18 depending on the results that Fisher -- that form the</p> <p>19 basis for -- for Fisher's derivation. I mean it's</p> <p>20 a --</p> <p>21 It is based on a hypergeometric distribution</p> <p>22 and it's exact from that. The chi-square by</p> <p>23 comparison is based on the idea that -- you know, that</p> <p>24 it becomes approximately a chi-square distribution, so</p> <p>25 there's an approximation involved with that. And why</p>

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<p style="text-align: right;">Page 186</p> <p>1 he called it an exact test is because there was not an 2 approximation involved. 3 Q. Do you disagree with Professor Berkson's 4 view that the problem with Fisher's is that you're 5 essentially combining discrete statistics with fixed 6 significance levels -- significance levels? 7 A. Well I think -- yeah. I mean that -- that 8 is a problem. That is, I think, a different -- 9 different problem because it is discrete. If you're 10 comparing at exactly the .05 level, the discrete 11 probabilities that it can take may not correspond to 12 exactly the .05. 13 Q. Yeah. 14 A. So it may go from .04 to .06, so you'd 15 reject the .04 but not the .06. 16 Q. That's a problem. 17 A. There's a space in there, so there is -- 18 there is a little bit of an ambiguity there. It 19 may -- 20 Well not it's ambiguous. It's either less 21 or not. 22 Q. Yeah. 23 A. But there is -- there is a bit of a -- of 24 a -- of a problem of comparing exactly because it's 25 not a continuous distribution.</p>	<p style="text-align: right;">Page 188</p> <p>1 traditional threshold of 0.05, and it rendered it non- 2 significant using Fisher's. That's exactly what 3 Berkson describes in his article of -- in his praise 4 of the exact test; correct? 5 A. As I say, I don't remember what -- what 6 Berkson -- Berkson's issue was. If that was his 7 issue, that would be an issue, and that, I mean -- 8 Q. That's the issue we just talked about when 9 you said -- 10 A. Yeah, yeah. That -- that is -- that is an 11 issue -- 12 Q. Okay. 13 A. -- associated with that test. I mean any 14 way you cut it, it's very close to the line. Even -- 15 even the chi-square was, what, point -- .048. 16 Q. Yeah. 17 A. That's not way out in the wild blue yonder 18 somewhere, that's really -- that is close to the line, 19 too. 20 Q. Agreed. 21 A. They're both, you know, close to the line. 22 Q. But in your conclusions of your report, one 23 of your rationales for concluding that the McGovern 24 study is not valid is because the p-value is not 25 significant; correct?</p>
<p style="text-align: right;">Page 187</p> <p>1 Q. And that's a problem with Fisher's test. 2 A. I don't know if it's a problem. It's -- 3 Q. It's a ramification of the test. 4 A. It's an issue, yes. 5 Q. Okay. And in light of that, according to 6 Berkson, Fisher's may result in the rejection of 7 p-values that are very close to significant but 8 ultimately render them non-significant. 9 A. That's right. Yeah. You could -- you could 10 have that. 11 Q. So in this -- 12 A. So in the example I just stated, I mean it 13 could be if that's the situation involved, you would 14 only reject at the .04, and so there's that little -- 15 Q. Yeah. 16 A. -- gap. 17 Q. Isn't that precisely the circumstance here, 18 because when you analyzed the remixed data using 19 chi-squared, you calculated a p-value of 0.0480; 20 correct? 21 A. I guess that's what it was, yeah. 22 Q. And then when you used Fisher, it went to 23 0.0507, so it took -- it took a p-value -- 24 A. Yes. 25 Q. -- that was significant, just below the</p>	<p style="text-align: right;">Page 189</p> <p>1 MR. GORDON: Object to the form of the 2 question. 3 A. That the p-value -- 4 Well it is what it is. 5 Q. Well on page six of your -- 6 A. I mean -- 7 Q. -- report in the "Conclusions regarding the 8 McGovern et al. findings" you say, "Reasons why the 9 McGovern et al. conclusions are not valid are: 10 "1." And the very last clause of that 11 number one is, "...which is close but not 12 statistically significant." 13 A. Yes. So that is the difference because it 14 doesn't achieve statistical significance; it's very 15 close to the line. 16 Q. And we just agreed that if you used 17 chi-squared it would be significant. 18 A. Yes. 19 Q. And we also just agreed that one of the 20 issues or ramifications of using Fisher's is that 21 values that are significant, -- 22 A. No. 23 Q. -- just below the conventional line of 24 statistical significance, may be deemed non- 25 significant by applying Fisher.</p>

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<p style="text-align: right;">Page 190</p> <p>1 A. No, that's not -- that's not what I said. 2 They could be close to the line, but that -- that 3 doesn't mean they're statistically significant. If 4 they're -- if they're not -- 5 If they don't cross the line, they're not 6 significant. 7 Q. Okay. So -- 8 But I'm going to back up because we just 9 talked about how one ramification of using Fisher's, 10 because there are discrete statistics with fixed 11 significance levels, -- 12 A. Yeah. 13 Q. -- that a statistic that is just below the 14 line of statistical significance, in the .04 range -- 15 A. Well if it's below .05 -- 16 Q. Yes. 17 A. -- it's significant, so don't you mean just 18 above? 19 Q. Well Fisher's would bring it just above; 20 correct? 21 A. Fisher's would bring it above, -- 22 Q. Yes. 23 A. -- but there -- 24 The problem is is that you can -- there 25 would not be a corresponding table that would give you</p>	<p style="text-align: right;">Page 192</p> <p>1 A. That's right. 2 Q. One of Berkson's critiques, whether or not 3 you've read the article, you appeared to agree that 4 there's an issue with combining discrete statistics 5 with fixed significance levels; correct? 6 A. I'm -- 7 Q. You said that was a ramification of using 8 Fisher's. 9 A. A ramification, -- 10 Q. Yes. 11 A. -- not necessarily a -- 12 It's a problem with what you're -- with what 13 you're trying to do. It is an issue with discrete -- 14 discrete probability values. 15 Q. And an implication of that is that p-values 16 that would otherwise be nominally significant, just 17 below the conventional limit of .05, would be rendered 18 non-significant above .05; correct? 19 A. No. 20 Q. So you disagree with Joseph Berkson. 21 A. I don't think that's -- 22 I doubt that's what he is saying. I mean 23 the premise of what you just said was that the value 24 would be significant. Right? Isn't that what you 25 said?</p>
<p style="text-align: right;">Page 191</p> <p>1 exactly .05, so that's not to say that, you know, it's 2 not -- it is or isn't significant. It doesn't cross 3 the line, which is the criteria for being 4 statistically significant. 5 Q. Okay. I'm going to try to back up again. 6 Your conclusion here on page six of your 7 report -- 8 A. Yeah. 9 Q. -- says that one of the reasons the McGovern 10 study is not valid is because the p-value is close to 11 but not statistically significant; correct? 12 A. That's right. The p-value that I'm talking 13 about -- 14 Q. I just want to establish that. 15 A. -- is .05 -- 16 Q. 507. 17 A. 507. 18 Q. Correct. 19 A. That's greater than .05. 20 Q. We've also established that when you apply 21 chi-squared to the data derived from Albrecht 10 and 22 McGovern seven -- 16, that the p-value is 0.048; 23 correct? 24 A. That's right. 25 Q. Just below statistical significance.</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. I said if you have a -- for example, a 2 p-value of 0.048, which is significant -- 3 A. That is significant, -- 4 Q. Yeah. 5 A. -- but it's less than .05. It's not .05. 6 Q. Well it's significant because it's less than 7 .05; correct? 8 A. Exactly. 9 Q. Okay. So I think we might be missing each 10 other. 11 A. So -- 12 Q. So -- 13 A. So I -- 14 How exactly did you say that statement 15 again, -- 16 Q. Okay. 17 A. -- which is what my problem is? 18 Q. Okay. So when you apply chi-squared -- 19 A. Yeah. 20 Q. -- to the reanalyzed data, we get a p-value 21 of 0.048, correct, which is below -- 22 A. That's -- that's an approximate p-value. 23 Q. Yes. 24 A. That approximate p-value is less than .05. 25 Q. And it's statistically significant because</p>

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<p style="text-align: right;">Page 194</p> <p>1 it's below --</p> <p>2 A. It's below.</p> <p>3 Q. -- 0.05, which is the conventional line for</p> <p>4 significance.</p> <p>5 A. That's -- that -- that is one of the -- one</p> <p>6 of the thoughts used, yes.</p> <p>7 Q. Yes. When you apply Fisher's, it goes from</p> <p>8 0.048 to 0.0507; correct?</p> <p>9 A. That's right.</p> <p>10 Q. And one of the issues with Fisher's is</p> <p>11 that it's combining discrete statistics with fixed --</p> <p>12 A. Yeah.</p> <p>13 Q. -- significance levels; right?</p> <p>14 A. Well it has --</p> <p>15 Q. We said that three times.</p> <p>16 A. -- significant value, yeah.</p> <p>17 Q. Okay. And the implication of doing that is</p> <p>18 what you said earlier where a p-value of .04 could</p> <p>19 then become non-significant by applying Fisher's.</p> <p>20 A. No. The .04 doesn't --</p> <p>21 It's not the .04 is going to this. They're</p> <p>22 two different -- completely different ways in which</p> <p>23 these things are computed, so one does not change.</p> <p>24 Q. Okay. Would you agree that chi-squared is</p> <p>25 better for larger sample sizes --</p>	<p style="text-align: right;">Page 196</p> <p>1 reasonably large, greater than five is one rule of</p> <p>2 thumb, --</p> <p>3 Q. Yeah.</p> <p>4 A. -- and then -- then it does pretty --</p> <p>5 pretty --</p> <p>6 The difference is pretty small.</p> <p>7 Q. What --</p> <p>8 So in terms of just talking about</p> <p>9 population, --</p> <p>10 A. Uh-huh.</p> <p>11 Q. -- what is a large population in your view?</p> <p>12 MR. GORDON: Object to the form -- object to</p> <p>13 the form of the question.</p> <p>14 Q. So does it depend on what the expected value</p> <p>15 would be, or could you determine that, okay, 5,000</p> <p>16 persons is a large population, or, you know, 2,000 is</p> <p>17 large or 10 --</p> <p>18 You know, I'm just trying to understand.</p> <p>19 Because in your report you say the McGovern population</p> <p>20 is relatively small, so I'm trying to kind of</p> <p>21 contrast, well, what's a large population in your</p> <p>22 view?</p> <p>23 A. Well it's relatively small because the</p> <p>24 number of infections in the -- in -- in one of the</p> <p>25 groups is like, what, three -- three or four depending</p>
<p style="text-align: right;">Page 195</p> <p>1 A. I wouldn't say it's better.</p> <p>2 Q. -- than Fisher?</p> <p>3 It's equally as good?</p> <p>4 A. There -- yeah, for large sample size --</p> <p>5 Well the results will -- will agree much</p> <p>6 better as the sample size increases.</p> <p>7 Q. Is chi-squared better or equally as good as</p> <p>8 Fisher's when using a well-balanced table?</p> <p>9 A. "Well-balanced table," what do you mean?</p> <p>10 Q. I -- I -- I guess two arms that have</p> <p>11 approximately the same number of data.</p> <p>12 A. It's --</p> <p>13 I don't know if it's better or -- better or</p> <p>14 worse. How much --</p> <p>15 It depends on the balance. It depends --</p> <p>16 what's particularly critical is the -- the expected</p> <p>17 number --</p> <p>18 Q. Yes. I'm going to go --</p> <p>19 A. -- in the cell, yeah.</p> <p>20 Q. I'll get here.</p> <p>21 But you do say in your report that</p> <p>22 chi-squared works well for comparing proportions when</p> <p>23 the sample size is large; right?</p> <p>24 A. That's right. When the -- when the -- when</p> <p>25 the numbers in all of the cells of the tables are</p>	<p style="text-align: right;">Page 197</p> <p>1 on which tabulation it is, so it's less than five.</p> <p>2 Q. So --</p> <p>3 A. So it's that value --</p> <p>4 So I mean 5,000 seems like a large</p> <p>5 population, but if you're looking at an effect that</p> <p>6 occurs one-tenth of one percent of the time --</p> <p>7 Q. Uh-huh.</p> <p>8 A. -- or less than that, then the numbers of</p> <p>9 infected start getting pretty small.</p> <p>10 Q. Got it.</p> <p>11 So do you agree or disagree with this view</p> <p>12 that you can apply Fisher's or chi-squared based on</p> <p>13 one option, which are expected values, and another</p> <p>14 option, which is size of population, just raw</p> <p>15 population?</p> <p>16 A. Just raw population I don't think is as</p> <p>17 critical as -- as values in -- in individual cells.</p> <p>18 That's -- that's -- that's a much more important --</p> <p>19 Q. So --</p> <p>20 A. -- factor than the total size.</p> <p>21 Q. Do you disagree with The Handbook of</p> <p>22 Biostatistics which states that "I recommend you use</p> <p>23 Fisher's exact test when the total sample size is less</p> <p>24 than a thousand?"</p> <p>25 A. I have to read the whole entry in the --</p>

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<p style="text-align: right;">Page 198</p> <p>1 But that doesn't sound quite right. I mean</p> <p>2 I think there would --</p> <p>3 You could have the total sample size be less</p> <p>4 than a thousand and if it's -- you know, if the</p> <p>5 balance among cells is such that the expected values</p> <p>6 of the fields are reasonably large, chi-square would</p> <p>7 do reasonably well.</p> <p>8 (Exhibit 20 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. SACCHET:</p> <p>11 Q. Turning to the last page of the document,</p> <p>12 professor, the citation is "McDonald, J.H. 2014.</p> <p>13 Handbook of Biological Statistics (3rd edition)." Do</p> <p>14 you see that?</p> <p>15 A. Where is this?</p> <p>16 Q. On the last -- on the last page in the most</p> <p>17 full paragraph that's three lines long, the citation</p> <p>18 says this document may be cited as "McDonald, J.H.</p> <p>19 2014. Handbook of Biological Statistics (3rd</p> <p>20 edition)."</p> <p>21 A. Okay.</p> <p>22 Q. Do you see that?</p> <p>23 A. Yeah.</p> <p>24 Q. Okay. And if you go to the first page of</p> <p>25 the document --</p>	<p style="text-align: right;">Page 200</p> <p>1 Fisher's exact test when the sample size is less than</p> <p>2 a thousand; correct?</p> <p>3 A. Yes.</p> <p>4 Q. Do you disagree with the implication of that</p> <p>5 statement, which is you don't need to use Fisher's</p> <p>6 exact test when the sample -- when the sample size is</p> <p>7 greater than a thousand?</p> <p>8 A. I don't think it says that.</p> <p>9 Q. What would it mean when it says it</p> <p>10 recommends to use it when it's less than a thousand?</p> <p>11 That doesn't mean that it's not --</p> <p>12 A. It doesn't -- it doesn't say what to do when</p> <p>13 it's greater than a thousand.</p> <p>14 Q. Okay. But it's your view that you don't</p> <p>15 apply chi-squared if it's greater than a thousand just</p> <p>16 as a raw number?</p> <p>17 A. I don't think it's particularly --</p> <p>18 It doesn't say whether or not -- or not. I</p> <p>19 mean if it's greater than a thousand, there are</p> <p>20 circumstances where I think it's still better to use.</p> <p>21 Q. You've applied chi-squared in populations of</p> <p>22 less than a thousand; haven't you?</p> <p>23 A. I probably have, yeah.</p> <p>24 Q. Is there a reason why in those articles you</p> <p>25 did so but in this report you don't?</p>
<p style="text-align: right;">Page 199</p> <p>1 A. Okay.</p> <p>2 Q. -- there's a "Summary" section of when to</p> <p>3 use a null hypothesis and how the test works; right?</p> <p>4 A. Yes.</p> <p>5 Q. And under the "When to use it," the very</p> <p>6 last paragraph starts with "Fisher's exact test is</p> <p>7 more accurate" blah, blah, blah; right? The very --</p> <p>8 the last paragraph of the --</p> <p>9 A. Yes.</p> <p>10 Q. -- section there.</p> <p>11 A. Yes.</p> <p>12 Q. The second sentence says, "I recommend you</p> <p>13 use Fisher's exact test when the total sample size is</p> <p>14 less than 1000..."</p> <p>15 A. Okay.</p> <p>16 Q. So is it wrong to conclude that you don't</p> <p>17 need to use Fisher's exact test when the sample size</p> <p>18 is greater than a thousand?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. I'm sorry, could you repeat that?</p> <p>22 Q. So this paragraph is comparing the use of</p> <p>23 Fisher's exact test to chi-squared in the G test.</p> <p>24 A. Yes.</p> <p>25 Q. And this handbook states that you should use</p>	<p style="text-align: right;">Page 201</p> <p>1 A. Well because the numbers were -- in the</p> <p>2 cells were bigger.</p> <p>3 Q. Okay. I just want to make sure that that's</p> <p>4 true. So --</p> <p>5 A. Well I don't if I --</p> <p>6 I've published a lot of papers, I don't know</p> <p>7 if I made a mistake in some, but that's generally what</p> <p>8 I do. If it's -- if it's a small number, I'll do the</p> <p>9 exact.</p> <p>10 (Exhibit 21 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. SACCHET:</p> <p>13 Q. Did you author this study, professor?</p> <p>14 A. I am one of the authors on this study.</p> <p>15 Q. Okay.</p> <p>16 A. Fairly far down the list. Okay.</p> <p>17 Q. The last paragraph in the right-hand column</p> <p>18 on the first page says that "Of the initial 1,002</p> <p>19 infants enrolled, 880 were included..." Do you see</p> <p>20 that?</p> <p>21 A. Yes.</p> <p>22 Q. If you turn to internal page 785, --</p> <p>23 A. Yes.</p> <p>24 Q. -- the last paragraph in the left-hand</p> <p>25 column starts "A major strength..." Do you see that?</p>

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<p style="text-align: right;">Page 202</p> <p>1 A. Yes.</p> <p>2 Q. "A major strength of our study is that we</p> <p>3 collected extensive respiratory symptom data, material</p> <p>4 asthma allergy histories, and housing characteristic</p> <p>5 information on a large population at high risk for</p> <p>6 developing asthma." Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Was that the large population of eight</p> <p>9 hundred some infants that you analyzed in this study?</p> <p>10 A. Yeah. I mean the reference there I -- I</p> <p>11 think is towards the size of the study in comparison</p> <p>12 to other studies of children's health and airborne</p> <p>13 disease.</p> <p>14 Q. Well you conclude, aside from the Augustine</p> <p>15 2017 study, that the McGovern study is the only</p> <p>16 observational data at hand regarding the use of the</p> <p>17 Bair Hugger or a conductive warming device in deep</p> <p>18 joint infections; correct?</p> <p>19 A. Okay. Yeah.</p> <p>20 Q. And that study had approximately 1400</p> <p>21 patients; correct?</p> <p>22 A. Yes.</p> <p>23 Q. And in that study you're calling it</p> <p>24 relatively small, but in this study you're calling a</p> <p>25 population of 800 persons large.</p>	<p style="text-align: right;">Page 204</p> <p>1 terms of the size of the study and whether or not it</p> <p>2 was big enough to address the particular hypothesis</p> <p>3 that was being -- that was being proposed in the -- in</p> <p>4 the proposal.</p> <p>5 Q. So it's your view that it's a better metric</p> <p>6 to use expected values than actual values, correct, to</p> <p>7 determine whether you apply Fisher's instead of</p> <p>8 chi-squared?</p> <p>9 A. The -- the -- the typical rule of thumb</p> <p>10 depends on the expected. In my own bias I've found</p> <p>11 that sometimes the observed number can be relevant as</p> <p>12 well.</p> <p>13 Q. So based on your own bias, you relied on the</p> <p>14 actual values reported in the study itself as opposed</p> <p>15 to the expected values that most statisticians rely on</p> <p>16 to determine whether to apply Fisher or not.</p> <p>17 A. Yeah. That's probably less commonly used on</p> <p>18 the observed values, but I prefer to do that because I</p> <p>19 think in this case, actually, the expected values</p> <p>20 are -- are greater, I -- I believe, than -- than --</p> <p>21 than the nominal five, if that's the rule you're</p> <p>22 using.</p> <p>23 Q. The rule of thumb.</p> <p>24 A. Yeah. If that's the rule you're using,</p> <p>25 that --</p>
<p style="text-align: right;">Page 203</p> <p>1 A. Well we're -- we're talking about two</p> <p>2 different things. It's small because what's -- in the</p> <p>3 Hot Dog group there are only three or four infections.</p> <p>4 Q. So the expected value -- the actual value.</p> <p>5 A. So if we're looking at -- if you're --</p> <p>6 If you -- what you want to do is design a --</p> <p>7 an experiment that really addresses the question of</p> <p>8 whether it reduces the rate of infection, 1400 is --</p> <p>9 it's arguable about whether that is large enough a</p> <p>10 study to do that.</p> <p>11 Q. So it's unclear whether it's large or small.</p> <p>12 A. Well I don't recall -- I --</p> <p>13 I never saw a power analysis of this study.</p> <p>14 And if you could show me one, I'd be glad to -- glad</p> <p>15 to review it.</p> <p>16 Q. So you never --</p> <p>17 A. But -- but the -- the study was not designed</p> <p>18 in the -- in the typical way that you would design a</p> <p>19 study if you were seeking NIH funding or something</p> <p>20 like that where you would be required to generate the</p> <p>21 sample size.</p> <p>22 Q. So you haven't --</p> <p>23 A. That's what would be required, and that</p> <p>24 would determine, you know, the -- the -- that would</p> <p>25 determine -- be more relevant, it seems to me, in</p>	<p style="text-align: right;">Page 205</p> <p>1 I haven't read this complete article. That</p> <p>2 doesn't seem to be what the person that wrote this</p> <p>3 article for Biological Statistics is using.</p> <p>4 Q. You would agree, though, the general rule of</p> <p>5 thumb with respect to implying -- employing Fisher's</p> <p>6 exact test is whether the expected value is under</p> <p>7 five; correct?</p> <p>8 A. Yeah. I mean there -- there's a difference,</p> <p>9 you understand, between recommending the choice, the</p> <p>10 extra calculation that's involved with doing Fisher</p> <p>11 exact as opposed to the easier calculation of doing</p> <p>12 chi-square; they recommended doing it based on the</p> <p>13 expected value being less than five.</p> <p>14 Q. Uh-huh.</p> <p>15 A. That's not to say that it's wrong to do the</p> <p>16 Fisher's exact test otherwise.</p> <p>17 Q. If you did an expected value calculation</p> <p>18 based on the populations reported in the McGovern</p> <p>19 study, it very well could exceed five for each arm of</p> <p>20 the study; correct?</p> <p>21 A. It could, yeah.</p> <p>22 Q. But you --</p> <p>23 A. We can do it. I --</p> <p>24 Q. I can --</p> <p>25 But you agree that that's possible.</p>

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<p style="text-align: right;">Page 206</p> <p>1 A. Yes.</p> <p>2 Q. And you didn't do it.</p> <p>3 A. I think I did look at it. I think it is a</p> <p>4 little bit greater, the expected value. But based</p> <p>5 on -- as I say, I -- my --</p> <p>6 What I have found very often, that the</p> <p>7 difference can be larger than I like depending on the</p> <p>8 observed number.</p> <p>9 Q. And --</p> <p>10 A. And in fact you see in my --</p> <p>11 Q. Yeah.</p> <p>12 A. -- report there's a difference in</p> <p>13 p-values --</p> <p>14 Q. And --</p> <p>15 A. -- and that's why I did the Fisher. And I</p> <p>16 find a difference.</p> <p>17 Q. Yeah. You -- you use Fisher instead of</p> <p>18 chi-squared; correct?</p> <p>19 A. That's right.</p> <p>20 Q. Even though the expected value is above</p> <p>21 five.</p> <p>22 A. That's right.</p> <p>23 Q. Okay.</p> <p>24 A. As I said, I mean it's not a --</p> <p>25 It's a rule of thumb. It's not a --</p>	<p style="text-align: right;">Page 208</p> <p>1 did the approximation break down, and it particularly</p> <p>2 breaks down if the expectation is small. My</p> <p>3 contention is is that it breaks down also to some</p> <p>4 extent when the observed values are small even though</p> <p>5 the expected values may be large.</p> <p>6 MR. SACCHET: We're going to mark another</p> <p>7 exhibit here.</p> <p>8 (Exhibit 22 was marked for</p> <p>9 identification.)</p> <p>10 A. The discreteness, for example, that we were</p> <p>11 just talking about would also come into play to some</p> <p>12 extent on chi-square, because I mean whenever you're</p> <p>13 dealing with integers, the -- the chi-square</p> <p>14 statistics that you -- that you get at the end is only</p> <p>15 going to take discrete values, it's not going to take</p> <p>16 a complete -- a continuum of values. So the</p> <p>17 particular criticism that -- that comes into play with</p> <p>18 Fisher's also, I would say, comes into effect to some</p> <p>19 extent on chi-square.</p> <p>20 Q. This --</p> <p>21 If you turn to the last page of this</p> <p>22 document, professor, is also part of McDonald's 2014</p> <p>23 Handbook on Biological Statistics; correct?</p> <p>24 A. Apparently.</p> <p>25 Q. Last page of the document. Do you see that</p>
<p style="text-align: right;">Page 207</p> <p>1 Q. You didn't follow the rule of thumb.</p> <p>2 A. I didn't follow the rule of thumb. I</p> <p>3 followed my own rule of thumb.</p> <p>4 Q. And that's contrary to generally accepted</p> <p>5 methods; correct?</p> <p>6 A. Well it's --</p> <p>7 Q. It's a rule of thumb.</p> <p>8 A. It's a rule of thumb that's sometimes</p> <p>9 applied. I mean you apply --</p> <p>10 Who is this, McDonald --</p> <p>11 Q. Yeah.</p> <p>12 A. -- in Exhibit 20?</p> <p>13 Q. Handbook of Biostatistics.</p> <p>14 A. Yeah. And McDonald is using a different</p> <p>15 rule of thumb. He's not --</p> <p>16 Q. Oh --</p> <p>17 A. At least in that first paragraph. I haven't</p> <p>18 read the whole thing.</p> <p>19 Q. He uses the same rule. I'll give you the</p> <p>20 other section of the handbook.</p> <p>21 A. Yeah. Well it's all -- it's all right. I</p> <p>22 mean I know there's -- there's a slight difference in</p> <p>23 how the rule of thumb is sometimes -- sometimes</p> <p>24 applied, but it's a rule of thumb that applies to the</p> <p>25 approximation. What does the approximation -- when</p>	<p style="text-align: right;">Page 209</p> <p>1 citation in the third kind of --</p> <p>2 A. Yeah, appears to be.</p> <p>3 Q. Yeah. And if you turn to page four of the</p> <p>4 document under "Similar tests" --</p> <p>5 Do you see that heading?</p> <p>6 A. Yes.</p> <p>7 Q. In the third paragraph, the very first line</p> <p>8 says, "The usual rule of thumb is that you should use</p> <p>9 the exact test when the smallest expected value is</p> <p>10 less than 5...;" correct?</p> <p>11 A. Where did you see this?</p> <p>12 Q. Are -- are you on page four? On the very</p> <p>13 top of the document there's pages X through seven.</p> <p>14 Are you on page four?</p> <p>15 A. Yeah. Which paragraph were you on?</p> <p>16 Q. Was I looking at the wrong document?</p> <p>17 There's a heading called "Similar tests."</p> <p>18 A. That's right.</p> <p>19 Q. Okay. And then in the -- I guess it's the</p> <p>20 fourth paragraph because the first line just a sole</p> <p>21 line, the paragraph begins, "The usual rule of</p> <p>22 thumb" --</p> <p>23 A. Oh, okay.</p> <p>24 Q. -- "is that you should use the exact test</p> <p>25 when the smallest expected value is less than 5..."</p>

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<p style="text-align: right;">Page 210</p> <p>1 A. That's right. Yeah, I -- I thought you were 2 referring to the third paragraph. 3 Okay. Yes. 4 Q. So that that corroborates the fact that in 5 this handbook the rule of thumb is that the expected 6 value should be less than five to apply Fisher's. 7 A. Yeah, which is what I -- which is what I 8 said, you know, -- 9 Q. Okay. 10 A. -- a few minutes ago. 11 Q. Okay. As to the p-value that you calculated 12 using Fisher's instead of chi-squared, on the data 13 derived from Albrecht 10 and McGovern 16 the p-value, 14 as we stated, is 0.0507; correct? 15 A. That's the value I got, yes. 16 Q. And the difference between that p-value and 17 the p-value when you use chi-squared on the reanalyzed 18 data of 0.048 is a matter of a thousandth of a decimal 19 place; correct? 20 A. Well it's point -- it's two -- 21 It's a difference of .2 -- .027; right? 22 Q. I've got a difference of .0009. 23 A. I thought we were comparing -- 24 Q. Let's see. The difference between .0507 -- 25 A. And .048.</p>	<p style="text-align: right;">Page 212</p> <p>1 the definition of it. 2 Q. It's a conventional line; correct? 3 A. It's the line that's often used. It's 4 obviously arbitrary, but it's the one that is very 5 often used. 6 Q. You agree that it's arbitrary. 7 A. Oh, yeah. 8 Q. And do you agree with The American 9 Statistical Association's recent statement that the 10 confidence levels of five percent and 10 percent are, 11 quote, "at best useful conventions?" 12 MR. GORDON: Object to the form of the 13 question. 14 A. I mean they're -- they're conventions that 15 are often used, yeah. 16 Q. Do you agree with the statement that they 17 are at best useful conventions? 18 MR. GORDON: Same objection. 19 A. That sounds -- I -- 20 I think I would agree with that. 21 Q. Are you aware that certain peer-reviewed 22 journals have recently decided to ban the use of 23 p-values? 24 MR. GORDON: Object to the form of the 25 question, lack of foundation.</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. .048. Yeah. 2 A. Well that's a difference -- 3 Q. I don't think mine's right. 4 A. -- of .0027. 5 Q. .0027. 6 A. Yeah. 7 Q. And that is, in percentage value, .27 8 percent; correct? 9 A. Correct. 10 Q. And as a raw figure it's -- forgive my 11 mathematical ignorance -- two-thousandths of a decimal 12 point? 13 A. Two -- 14 Well it rounds up to, I think, three. But 15 anyway, yeah. 16 Q. Okay. Three-thousandths of a decimal point? 17 A. Right. 18 Q. And that's the basis by which you say that 19 the McGovern data goes from non-significance to 20 significance -- or significance to non-significance; 21 correct? 22 A. No. I mean the definition of -- of 23 significance, is it above or below the line? 24 Q. That's the conven -- 25 A. Critically thinking, that's the -- that's</p>	<p style="text-align: right;">Page 213</p> <p>1 A. I'm aware that some journals some time 2 ago -- I'm not sure, I thought they had retracted on 3 that somewhat more recently, but there was a -- there 4 was a period of time where they went through -- some 5 journals went through that -- the thing about -- 6 about -- about the p-values. 7 Q. Do you know Ron Wasserstein, who I think is 8 the president of the ASA? 9 A. I don't know him, -- 10 Q. Okay. 11 A. -- no. 12 Q. Would you agree with his statement that the 13 p-value is not intended to be a substitute for 14 scientific reasoning? 15 MR. GORDON: Object to the form of the 16 question and lack of foundation. 17 A. You know, I'm -- I'm not sure what the whole 18 statement was that he is -- that he is talking about. 19 I mean certainly on the surface that -- 20 It's not -- it's not the sole basis for 21 scientific reasoning, is that what you're saying? I 22 mean -- 23 Q. His quote is the p-value is never intended 24 to be a substitute for scientific reasoning, end 25 quote.</p>

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<p style="text-align: right;">Page 214</p> <p>1 A. Okay.</p> <p>2 Q. Do you agree with that statement?</p> <p>3 A. Yeah, uh-huh.</p> <p>4 Q. And do you also agree with the statement</p> <p>5 that p-values -- a p-value of less than .05 is not a</p> <p>6 line that separates real results from false ones?</p> <p>7 A. Well certainly, yeah.</p> <p>8 Q. Okay. So if those --</p> <p>9 Well I'll ask you one more question. Do you</p> <p>10 agree that practices that reduce data analysis or</p> <p>11 scientific inference to mechanical bright-line rules,</p> <p>12 such as the p-value of being less than .05 for</p> <p>13 justifying scientific claims or conclusions, can lead</p> <p>14 to erroneous beliefs and poor decision-making?</p> <p>15 A. Yes.</p> <p>16 Q. One of your conclusions in this report is</p> <p>17 that the McGovern data is invalid because the p-value</p> <p>18 is .0507; correct?</p> <p>19 A. Well I think that's a --</p> <p>20 You're mixing -- you're mixing different --</p> <p>21 different issues here. McGovern, as I understand the</p> <p>22 way it's being used here, is to -- is not as a -- it's</p> <p>23 used to try to say that there is strong scientific</p> <p>24 evidence that infection rates for Bair Hugger are</p> <p>25 higher than the Hot Dog warmer.</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. Okay.</p> <p>2 A. I mean what I'm doing, if -- and what I --</p> <p>3 Part of what I'm commenting here and part of</p> <p>4 what I would disagree with is a comparison with what</p> <p>5 Samet is saying.</p> <p>6 Q. Okay. We'll get to that.</p> <p>7 A. Samet is saying that the evidence is very</p> <p>8 strong.</p> <p>9 Q. Okay.</p> <p>10 A. Okay? And what I'm saying is that it's not</p> <p>11 that strong, it's right on the cusp.</p> <p>12 Q. Are you aware that under the law, the</p> <p>13 Supreme Court of the United States of America has</p> <p>14 stated that statistically significant p-values are not</p> <p>15 necessary to determine causation?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question and lack of foundation.</p> <p>18 A. I -- I'm not familiar with -- with what the</p> <p>19 Supreme Court said or exactly what they were dealing</p> <p>20 with.</p> <p>21 Q. So your report does not account for the</p> <p>22 legal standard that applies to determinations of</p> <p>23 causation as a matter of law.</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question, lack of foundation.</p>
<p style="text-align: right;">Page 215</p> <p>1 Q. My question is just about this p-value which</p> <p>2 you use on page six of your report where you say, "The</p> <p>3 reasons why McGovern et al conclusions are not valid</p> <p>4 is because the p-value is close but not statistically</p> <p>5 significant." That's one of your conclusions; is that</p> <p>6 not correct?</p> <p>7 A. Well the -- my con -- yes, my --</p> <p>8 Well, what I'm saying is the evidence is not</p> <p>9 strong. Whether you say the p-value is .0507 --</p> <p>10 Q. Okay.</p> <p>11 A. -- or .048, those are not wildly small</p> <p>12 p-values to say that there is extremely strong</p> <p>13 evidence here of an association.</p> <p>14 Q. But you would agree that the fact that it's</p> <p>15 just over statistical significance does not mean that</p> <p>16 the results are invalid.</p> <p>17 A. The conclusions --</p> <p>18 My conclusions are not terribly different</p> <p>19 from either one of those p-values.</p> <p>20 Q. Okay. So whether --</p> <p>21 A. They're -- they're --</p> <p>22 Q. -- it's marginally significant or just over</p> <p>23 statistical significance does not matter.</p> <p>24 A. They're -- they're all -- both on the</p> <p>25 border.</p>	<p style="text-align: right;">Page 217</p> <p>1 A. Is that --</p> <p>2 Is the Supreme Court talking about a matter</p> <p>3 of -- matter of law, or you were -- you were stating</p> <p>4 it as -- as scientific -- as a scientific -- statement</p> <p>5 of scientific fact?</p> <p>6 Q. Quote, "A lack of statistically significant</p> <p>7 data does not mean that a medical expert has no</p> <p>8 reliable basis for inferring a causal link between a</p> <p>9 product and an adverse event," end quote.</p> <p>10 A. The lack of -- I -- I --</p> <p>11 I don't know.</p> <p>12 MR. GORDON: I'll object to the form of the</p> <p>13 question.</p> <p>14 A. Yeah. I don't really understand what --</p> <p>15 what they're -- what they're getting at. I would have</p> <p>16 to --</p> <p>17 Q. Would it help to see the statement?</p> <p>18 A. I'd have to review the statement. I mean</p> <p>19 how --</p> <p>20 What is it, a whole report?</p> <p>21 Q. It's a case, and we don't have time for you</p> <p>22 to read the whole case, but --</p> <p>23 A. I mean that's --</p> <p>24 I'd have to figure out what the case is</p> <p>25 talking about. It -- it's --</p>

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<p style="text-align: right;">Page 218</p> <p>1 I'm not a lawyer, obviously, and so I'm --</p> <p>2 I'm not sure what distinctions that they're -- that</p> <p>3 they're making. Their language is sometimes a little</p> <p>4 different.</p> <p>5 MR. SACCHET: Okay. Let's take a break.</p> <p>6 THE REPORTER: Off the record, please.</p> <p>7 (Recess taken.)</p> <p>8 BY MR. SACCHET:</p> <p>9 Q. Professor Holford, in your report you also</p> <p>10 note that applying Fisher's exact test on the data</p> <p>11 derived from Albrecht Exhibit 10 and McGovern Exhibit</p> <p>12 16 yields a confidence interval of .97 to 10.82;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. And essentially that .97 is just .03 away</p> <p>16 from the null value of one; correct?</p> <p>17 A. That's right.</p> <p>18 Q. So it's subject to this same debate about</p> <p>19 just over/just under.</p> <p>20 A. It's just -- it's just under the critical</p> <p>21 value.</p> <p>22 Q. Yes.</p> <p>23 A. I mean it corresponds --</p> <p>24 It's a little less because the p-value is a</p> <p>25 little high.</p>	<p style="text-align: right;">Page 220</p> <p>1 McGovern study; correct?</p> <p>2 A. That's right. It's statistically</p> <p>3 significant, but the -- but the -- but it's not a good</p> <p>4 estimate of what the risk is.</p> <p>5 Q. So it has double the variance as the</p> <p>6 confidence interval in the McGovern study.</p> <p>7 A. Well it's -- it seems to be double the --</p> <p>8 the range, the -- the -- the length of the -- of the</p> <p>9 confidence interval.</p> <p>10 Q. But you rely on this calculation with</p> <p>11 respect to arguing whether or not the</p> <p>12 thromboprophylaxis that was used in the McGovern study</p> <p>13 is in fact a confounding factor; correct?</p> <p>14 A. Well I'm --</p> <p>15 I was looking at the p-value. The p-value</p> <p>16 that I get associated with that is .006 --</p> <p>17 Q. Uh-huh.</p> <p>18 A. -- 4, so it's quite a small p-value. The</p> <p>19 estimate of what that effect is is quite imprecise</p> <p>20 because of -- you know, because of the range that we</p> <p>21 were just talking about.</p> <p>22 Q. It's more imprecise than the McGovern</p> <p>23 study's confidence interval that you critique.</p> <p>24 A. Well it's more imprecise in --</p> <p>25 In general what happens with the -- with</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. And you conclude that one of the issues with</p> <p>2 that confidence interval is it's essentially 10 points</p> <p>3 and therefore there's -- there could be unreliability</p> <p>4 to the data; correct?</p> <p>5 A. Well the estimate of the -- of the odds</p> <p>6 ratio is -- is not precise at all. I mean it's a</p> <p>7 ten-fold difference, ten-fold range.</p> <p>8 Q. So I was confused because when I read your</p> <p>9 report and I saw your real analysis of the Jensen</p> <p>10 data --</p> <p>11 Which you did applying Albrecht Exhibit 10;</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. -- the confidence interval of your</p> <p>15 calculation is 25 points wide.</p> <p>16 A. I forget what the range was. It was pretty</p> <p>17 wide.</p> <p>18 Where was it?</p> <p>19 Q. It's on page five.</p> <p>20 A. Page five. So you're referring to the 1.37</p> <p>21 to 25.49.</p> <p>22 Q. Yeah.</p> <p>23 A. Yeah. Yeah. It's not a very good estimate.</p> <p>24 Q. It's double the size of the confidence</p> <p>25 interval that you critique with respect to the</p>	<p style="text-align: right;">Page 221</p> <p>1 the -- with the confidence interval is it kind of</p> <p>2 depends on the logarithm, so it's more on the log</p> <p>3 scale, so that's part of what happens. I mean this</p> <p>4 odds ratio is 4.77, so it's quite a bit bigger than</p> <p>5 the odds ratios we were finding associated with Bair</p> <p>6 Hugger use. So that's -- that's of course just a</p> <p>7 point estimate, and so we're talking about a higher</p> <p>8 range, so the range is going to be -- going to tend to</p> <p>9 be somewhat wider because -- because we're up there.</p> <p>10 And of course the -- the total sample size, total</p> <p>11 number of individuals involved is -- is quite a bit</p> <p>12 smaller than -- than -- because it -- it's just</p> <p>13 based --</p> <p>14 It comes out to be a subset of the -- of the</p> <p>15 Bair Hugger study because it's only the Bair Hugger</p> <p>16 period, so it's reduced in that way, and then the</p> <p>17 other thing is that it's not the entire period, it's</p> <p>18 just part of it, so we -- you're splitting that data</p> <p>19 set up. And so your total sample size has gone down,</p> <p>20 and that increases the -- that decreases the sample</p> <p>21 size and in general makes the estimates less precise.</p> <p>22 Q. But there's no doubt that the confidence</p> <p>23 interval in this Jensen reanalysis, which is in your</p> <p>24 report on page five, is double the width of the</p> <p>25 McGovern confidence interval; correct?</p>

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<p style="text-align: right;">Page 222</p> <p>1 A. That seems to be what it is, yes. 2 Q. That is what it is. 3 A. Okay. Yeah. 4 Q. Your report also states that when applying 5 Albrecht Exhibit 10 and McGovern Exhibit 16, that the 6 p-value -- or that the odds ratio is 2.76 when using 7 Fisher's exact; correct? 8 A. Well that -- that -- yeah. And that -- 9 that's not -- 10 The -- the test, the Fisher's exact, has to 11 do with the p-value, not the -- not the estimate of 12 what the odds ratio is. 13 Q. So on page two of your report when you say 14 the odds ratio for this comparison is 2.76, where did 15 you get that from? 16 A. That's just a cross-product ratio for that 17 table. 18 Q. And is that -- okay. 19 So the 2.76 derives from Albrecht Exhibit 10 20 and McGovern Exhibit 16. 21 A. That's right. It's a tabulation of those 22 data. I mean it's -- 23 Yeah. 24 Q. And it's only accurate insofar as those 25 exhibits are accurate; correct?</p>	<p style="text-align: right;">Page 224</p> <p>1 A. Well it's the -- it's the -- two point -- 2 Where is that? Oh, here we are. Okay. 3 Yeah. That's based on this -- this table that is the 4 four out of 372 and 31 out of 1065. 5 Q. And where did you get that data? 6 A. That's from -- from -- 7 Was it Albrecht 10? 8 Q. Okay. You would agree that that odds ratio 9 is still above 2.0; correct? 10 A. Yes. 11 Q. Would you agree that an odds ratio of 2.0 is 12 often referred to as a doubling of the risk? 13 A. It -- it is, yeah. 14 Q. And -- and that means you're 50 percent more 15 likely to experience the outcome after exposure to the 16 variable than the count as actual? 17 MR. GORDON: Object to the form of the 18 question. 19 A. Well if -- what it would imply, if -- if -- 20 if the odds ratio was -- if the -- 21 The odds ratio is actually a ratio of odds. 22 The statement that you made as -- is re -- is 23 related -- you state it as a ratio of -- of risks, 24 which would typically mean a ratio of the -- of the 25 incidence rates.</p>
<p style="text-align: right;">Page 223</p> <p>1 A. Well the accuracy depends on -- on the -- on 2 the -- 3 Q. Cross product. 4 A. Well the point estimate is the cross 5 product. The -- the confidence interval depends on 6 this Fisher-like distribution. It's not -- 7 It's an exact kind of calculation that -- 8 that -- that's involved, but it's kind of a lengthy 9 calculation that roughly depends on the standard 10 error. 11 Q. So I might need to back up because I don't 12 know if I'm fully understanding what you're saying. 13 But the odds ratio reported in the McGovern study was 14 3.8; correct? 15 A. Yes. 16 Q. And then in your report on page two you say 17 the odds ratio for this comparison is 2.76, and 18 what -- 19 A. That's in the tabulation I used, yes. 20 Q. -- what data are you using to derive that 21 odds ratio? 22 A. The -- 23 MR. GORDON: Arithmetically, or the 24 underlying data? 25 MR. SACCHET: Arithmetically.</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. Okay. 2 A. So when the incidence rates are small, those 3 two are very similar, okay, and so they're roughly 4 used in that way. So an odds ratio of two, it's -- 5 strictly speaking it's twice the odds of getting an 6 infection, although it's going to be very close as -- 7 to -- to twice the incidence. 8 Q. Okay. 9 A. So if -- well if -- if you're saying that 10 the -- the Hot Dog is the norm and the odds ratio is 11 two, that would say that the Bair Hugger has twice the 12 risk. 13 Q. Okay. 14 A. That's how -- how you would roughly 15 interpret that statement. 16 Q. Okay. 17 A. Depending on whether or not -- whether that 18 statement is correct we might disagree on, but -- 19 Q. So if the incidence of disease in an exposed 20 group is more than twice the incidence in the 21 unexposed group, the probability that exposure to the 22 agent caused a similarly situated individual is also 23 greater than 50 percent; correct? 24 A. If -- if that estimate is -- is accurate, 25 that's roughly what it would -- what it would be --</p>

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<p style="text-align: right;">Page 226</p> <p>1 what it -- what it would mean. 2 Q. Thank you. 3 Okay. I'd like to talk a little bit about 4 the other section of your report which deals with the 5 time trend infection rates at Wansbeck, and I guess 6 really the -- the big header is "Infection rate 7 comparison among hospitals" starting on page three, at 8 the bottom of page three, and then continuing into 9 four and five. 10 So to be clear, in your report you note that 11 there is a .6 percent infection rate among NHS trust 12 in 2010 to 2015; correct? 13 A. Yes. 14 Q. And when you cite a 2.9 percent infection 15 rate at the top of page four, that is based also on 16 the Albrecht Exhibit 10 and McGovern Exhibit 16 data; 17 correct? 18 A. That's right. 19 Q. And to be clear, that infection rate as it 20 relates to Bair Hugger patients was during the 2008 21 and 2009 time period; correct? 22 A. That's correct. 23 Q. So you are comparing an infection rate of 24 Bair Hugger patients in 2008 and 2009 to an infection 25 rate from 2010 to 2015.</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. Okay. 2 A. And so I used the best data that I could get 3 ahold of to -- to see what the experience was at other 4 hospitals using Bair Hugger at this time to get a 5 comparison of how Wansbeck fit -- fit in with the -- 6 with the experience at other hospitals. 7 Q. Did you try to get data from 2008 to 2009? 8 A. I didn't have -- I didn't have a -- didn't 9 come across a good way of doing that. 10 Q. Okay. But you recognize that it's two 11 different time periods. 12 A. Yes, I do. Uh-huh. 13 Q. Are you aware of infection rates in the 14 United States as opposed to infection rates reported 15 by the NHS in the U.K.? 16 A. No. I don't know what the rates are in the 17 U.S. 18 Q. So you do not know whether the rates of 19 infection as reported in the McGovern study are 20 comparable to rates in the United States. 21 A. I don't have a direct es -- estimate of 22 rates in the United States. My assumption is that 23 they're not too different, but -- 24 Q. But -- 25 A. -- I don't know. I don't have the data.</p>
<p style="text-align: right;">Page 227</p> <p>1 A. That's right. 2 Q. They are two different time periods; 3 correct? 4 A. That's correct. 5 Q. That's an apples-to-orange comparison; isn't 6 it? 7 MR. GORDON: Object to the form of the 8 question. 9 Q. Let me put it this way: It's not externally 10 generalizable. 11 A. It's not -- 12 What do you mean? 13 Q. It's not externally valid. I mean if -- if 14 you're looking at a date range of 2010 to 2015, you 15 don't know for sure whether that -- 16 A. Yeah. 17 Q. -- infection rate should apply to prior 18 years; do you? 19 A. Well if -- if things are reasonably -- 20 I mean the -- the assumption there is that 21 there's not a huge temporal trend going on in 22 infection rates in the U.K., and so my -- my 23 assumption is -- I -- I didn't have -- 24 Ideally, I would have had the data for the 25 same years. I didn't.</p>	<p style="text-align: right;">Page 229</p> <p>1 Q. -- with respect to your analysis as to 2 whether the time trend data of infections as reported 3 in McGovern is out of control, as you say, that is 4 only as compared to hospitals in the U.K. from 2010 to 5 2015. 6 A. In terms of the magnitude of the effect, 7 that's -- that was one of the pieces of evidence that 8 I was -- that I was looking at. 9 Q. But it's only specific to hospitals in the 10 U.K. 11 A. That's right. I was using data in the U.K. 12 Q. Okay. 13 (Exhibit 23 was marked for 14 identification.) 15 BY MR. SACCHET: 16 Q. Professor Holford, is this a graph bearing 17 the title "Joint infection rate in BH unit sales by 18 year?" 19 A. Yes. 20 Q. Okay. And do you know what ICD codes are? 21 A. Yes. Those are disease codes for -- for 22 different diseases, yes, that are standardized. 23 Q. They relate to disease in the United States. 24 A. Are they only -- I don't -- I'm not sure 25 what -- what they use --</p>

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<p style="text-align: right;">Page 230</p> <p>1 I don't know what they use in the U.K. This</p> <p>2 is U.S. data, is it?</p> <p>3 Q. I'll represent to you that it is.</p> <p>4 A. Okay.</p> <p>5 Q. And there are three colored lines; correct?</p> <p>6 A. That's correct.</p> <p>7 Q. And to be clear, the title is "Joint</p> <p>8 infection rate...;" correct?</p> <p>9 A. "Joint" --</p> <p>10 Yes.</p> <p>11 Q. Of the graph.</p> <p>12 A. "Joint infection rate..."</p> <p>13 Q. Not like surgical-site infection or other</p> <p>14 type of infection, this is specific to joint</p> <p>15 infection; correct?</p> <p>16 A. That's right.</p> <p>17 Q. Okay. And the two orange-colored lines</p> <p>18 relate to infection rates; correct?</p> <p>19 MR. GORDON: Objection, lack of foundation.</p> <p>20 A. I don't know. I --</p> <p>21 Q. Do you see the legend?</p> <p>22 A. Oh, I see.</p> <p>23 Q. Do you see the legend at the bottom?</p> <p>24 A. Yeah. Okay.</p> <p>25 Q. And then the Y axis on the right side of the</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. So there's an infection rate --</p> <p>2 A. -- it's hard to read.</p> <p>3 Q. And I'm not going to focus on which line,</p> <p>4 you know, we need to focus on, I just want to</p> <p>5 establish that both lines depict infection rates --</p> <p>6 A. Okay.</p> <p>7 Q. -- equal to or greater than four but less</p> <p>8 than five in 2008; correct?</p> <p>9 A. Yeah.</p> <p>10 Q. Okay. And then in 2010 the dots appear to</p> <p>11 be the same, somewhere between four and five; correct?</p> <p>12 A. Right.</p> <p>13 Q. And in fact in 2011 they went up to</p> <p>14 approximately 4.5 and five; correct?</p> <p>15 A. Appears to, yeah.</p> <p>16 Q. Yeah. So if we can find the graph to the</p> <p>17 Bair Hugger study period, which is 2008 to 2010, based</p> <p>18 on this graph the infection rate is four percent or</p> <p>19 perhaps 4.5 percent; correct?</p> <p>20 A. Infection --</p> <p>21 MR. GORDON: Objection, lack of foundation.</p> <p>22 A. So I -- I mean what -- what do these -- what</p> <p>23 do the ICD codes --</p> <p>24 Q. ICD codes --</p> <p>25 I can't testify, but ICD codes, as you</p>
<p style="text-align: right;">Page 231</p> <p>1 graph is titled "Joint Infection Rates" and then it</p> <p>2 lists an ICD code; correct?</p> <p>3 A. Right.</p> <p>4 Q. Or codes. Correct?</p> <p>5 A. Right.</p> <p>6 Q. And those percentages range from zero to</p> <p>7 six, at least as depicted on the graph, correct, on</p> <p>8 the Y axis on the right-hand side?</p> <p>9 A. That's right.</p> <p>10 Q. Okay. And whichever --</p> <p>11 Well let's look at 2008, and that's when the</p> <p>12 Bair Hugger study period started; correct?</p> <p>13 A. 2008. Okay.</p> <p>14 Q. And the lower orange line, the dot there is</p> <p>15 approximately four percent; correct?</p> <p>16 A. Four percent.</p> <p>17 MR. GORDON: Again, lack of foundation.</p> <p>18 A. Seems to be.</p> <p>19 Q. And the dot above that is between four and</p> <p>20 five.</p> <p>21 A. Somewhere --</p> <p>22 Something, yeah.</p> <p>23 Q. Okay.</p> <p>24 A. What are the two lines? I don't</p> <p>25 understand, --</p>	<p style="text-align: right;">Page 233</p> <p>1 stated earlier, --</p> <p>2 A. Yeah.</p> <p>3 Q. -- relate to particular outcomes of disease.</p> <p>4 A. No. But what is ICD-9 -- 996.66?</p> <p>5 Q. I don't know the answer to that question,</p> <p>6 but I can tell you that 3M's corporate representative,</p> <p>7 Mr. Van Duren, testified that this graph depicts the</p> <p>8 rate of Bair Hugger segment penetration with the rate</p> <p>9 of joint infections.</p> <p>10 A. Okay. So these are some sort of --</p> <p>11 I'm having a hard time understanding what</p> <p>12 you're trying to show here --</p> <p>13 Q. I'm -- I'm --</p> <p>14 A. -- because, I mean, we've got two</p> <p>15 different -- two different lines of the infection</p> <p>16 rates --</p> <p>17 Q. So my question is --</p> <p>18 A. -- and when -- when I --</p> <p>19 I don't know what these two different lines</p> <p>20 are.</p> <p>21 Q. Okay. My question is simple.</p> <p>22 A. Okay.</p> <p>23 Q. Whichever line you choose, the infection</p> <p>24 rate, according to this graph, in 2008 and 2010 was</p> <p>25 4.0 or 4.5; --</p>

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<p style="text-align: right;">Page 234</p> <p>1 A. Okay.</p> <p>2 Q. -- is that correct?</p> <p>3 MR. GORDON: Objection, lack of foundation,</p> <p>4 assumes facts not in evidence, incomplete</p> <p>5 hypothetical.</p> <p>6 Q. According to this graph.</p> <p>7 A. Those numbers that are shown, I don't -- and</p> <p>8 as I say, I don't know what they are, you haven't told</p> <p>9 me what they are, there's not a legend here that</p> <p>10 exactly indicates what they are --</p> <p>11 Q. The graph is called "Joint infection</p> <p>12 rate...;" right?</p> <p>13 A. That's what it -- that's what it's called.</p> <p>14 Q. Okay.</p> <p>15 A. But I mean if you look up the ICD code,</p> <p>16 they're very specific on what -- what -- what they</p> <p>17 mean. They're -- they're pretty speci -- specific,</p> <p>18 and I just -- I don't know how those values -- how</p> <p>19 those codes compare with --</p> <p>20 I -- I mean I don't know where you're going</p> <p>21 with this, if you want to compare these values to the</p> <p>22 experience in -- in the U.K. or what -- what exactly</p> <p>23 you're -- you're looking at.</p> <p>24 Q. I'll -- I'll just cut to it. Based on this</p> <p>25 graph -- and I'll make the assumption that these I --</p>	<p style="text-align: right;">Page 236</p> <p>1 If you look at this graph, I mean those</p> <p>2 orange lines are not changing very much between 1996</p> <p>3 and 2012. Okay? They're pretty flat. And so my</p> <p>4 comparison of -- of these two periods for the U.K.,</p> <p>5 one of which was, what, --</p> <p>6 Q. Two thousand --</p> <p>7 A. -- two thousand --</p> <p>8 Let's see. Bair Hugger is '8 to '9 and the</p> <p>9 plot in this case, Fig. 1, has to do with '10 to '15.</p> <p>10 Okay. So based on this, it doesn't seem to be -- look</p> <p>11 to -- to my eyes to be a whole lot different</p> <p>12 between -- before 2010 and between '10 and '15.</p> <p>13 Q. Okay.</p> <p>14 A. Would you agree?</p> <p>15 Q. You assume, in calculating the deep joint</p> <p>16 infection rate in the NHS, that there was complete</p> <p>17 reporting practices among hospitals; correct?</p> <p>18 A. Yeah, that's my assumption. Yeah.</p> <p>19 Q. And if there were not complete reporting</p> <p>20 practices, those averages would be subject, again, to</p> <p>21 a data artifact; correct?</p> <p>22 A. Yes.</p> <p>23 Q. You said that you reviewed Dr. Reed's</p> <p>24 testimony; correct?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 235</p> <p>1 ICD codes relate to joint infection as the graph is</p> <p>2 entitled, --</p> <p>3 A. Okay.</p> <p>4 Q. -- the infection rate of four percent is</p> <p>5 higher than the infection rate reported by McGovern et</p> <p>6 al.</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question, lack of foundation, assumes facts not in</p> <p>9 evidence, incomplete hypothetical.</p> <p>10 A. Well I mean what I don't understand about</p> <p>11 your question is that you -- there's not a -- there's</p> <p>12 no evidence of how this definition of joint infection</p> <p>13 compares to what McGovern was looking at. What's the</p> <p>14 denominator? What are -- what are -- exactly are --</p> <p>15 I mean are these specific knee and hip</p> <p>16 surgeries? I don't -- I don't know.</p> <p>17 Q. Well just is --</p> <p>18 A. It doesn't say.</p> <p>19 Q. Okay. Assuming that it involves a different</p> <p>20 category of infections, just for the sake of argument,</p> <p>21 that's also a different group than looking at patients</p> <p>22 from 2010 to 2010, isn't it, when the McGovern study</p> <p>23 was about Bair Hugger patients from 2008 to 2009,</p> <p>24 2010?</p> <p>25 A. Well, but I think -- I mean it does say --</p>	<p style="text-align: right;">Page 237</p> <p>1 Q. And did you see where Dr. Reed said that</p> <p>2 "Not every trust puts in the data as we have</p> <p>3 established and the infection rates that they quote</p> <p>4 were very low. And in fact government advisors on</p> <p>5 infection have publicly written to say that their</p> <p>6 quotes -- they quote very low infection rates,</p> <p>7 unrealistically low, because the surveillance system</p> <p>8 is poor in many trusts."</p> <p>9 A. Okay. I mean it -- it may well be.</p> <p>10 Q. So if it may well be, the .6 percent rate</p> <p>11 that you report in your study may also well be subject</p> <p>12 to data artifact.</p> <p>13 A. The accuracy of -- of -- of that value</p> <p>14 depends on the accuracy of the data that were reported</p> <p>15 in the file that I looked at.</p> <p>16 Q. And in your report you relied on Mr.</p> <p>17 Reed's -- Dr. Reed's testimony regarding other subject</p> <p>18 matter; correct?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. Yes, some of the other subject matter. I</p> <p>22 mean I --</p> <p>23 Q. You have no reason to doubt Mr. Reed's</p> <p>24 testimony regarding the --</p> <p>25 A. I --</p>

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<p style="text-align: right;">Page 238</p> <p>1 Q. -- incomplete --</p> <p>2 A. Yeah. I really don't --</p> <p>3 I mean I have -- I have no reason to</p> <p>4 question pro or con the -- the quality of the -- of</p> <p>5 the U.K. data, the -- the NHS data.</p> <p>6 Q. Do you rely on Dr. Reed's testimony only</p> <p>7 when it supports your conclusions?</p> <p>8 A. No. It's just -- I -- I'm -- I mean I'm</p> <p>9 not --</p> <p>10 Dr. Reed is expressing his view on -- on</p> <p>11 the -- on those -- those NHS data. I have no basis to</p> <p>12 know one way or the other how good those data are.</p> <p>13 Q. So you have no basis to know one way or</p> <p>14 the --</p> <p>15 A. So I'm using their -- their data to get an</p> <p>16 idea of what the -- what the rates -- what the rates</p> <p>17 were, and those are the values that they reported.</p> <p>18 Q. Did you investigate whether there is</p> <p>19 complete reporting among hospitals in the NHS?</p> <p>20 A. No.</p> <p>21 Q. You simply assumed that there was complete</p> <p>22 reporting.</p> <p>23 A. I assume -- I assumed that the data --</p> <p>24 I mean the data are what they are.</p> <p>25 Q. You also assumed that hospitals that use the</p>	<p style="text-align: right;">Page 240</p> <p>1 down the specific devices that they use and if they</p> <p>2 use alternative devices.</p> <p>3 Q. You said you reviewed Dr. Reed's testimony;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. You didn't see in Dr. Reed's deposition</p> <p>7 where he made clear that there are hospitals that use</p> <p>8 both the Bair Hugger and conductive warming devices?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question, lack of foundation, assumes facts not in</p> <p>11 evidence.</p> <p>12 A. I don't know what he was referring to. I</p> <p>13 don't know if he was looking at the same data set that</p> <p>14 I was looking at.</p> <p>15 Q. Okay. Did you investi --</p> <p>16 A. So I don't know.</p> <p>17 Q. Did you investigate to see whether or not</p> <p>18 hospitals do use both devices beyond the documents</p> <p>19 that 3M provided you?</p> <p>20 A. I -- I didn't get any further information.</p> <p>21 I mean it wouldn't surprise me that -- that some</p> <p>22 hospitals -- I mean I don't --</p> <p>23 I don't know if this is exhaustive of all of</p> <p>24 the hospitals or just those that -- that -- that were</p> <p>25 indicated as having used Bair Hugger devices.</p>
<p style="text-align: right;">Page 239</p> <p>1 Bair Hugger do not use other warming devices; correct?</p> <p>2 A. That was --</p> <p>3 I mean the assumption was that the primary</p> <p>4 warmers that they were using in these hospitals was in</p> <p>5 fact the Bair Hugger.</p> <p>6 Q. In your report you state that 3M provided</p> <p>7 you with documents that delineated whether or not a</p> <p>8 hospital uses the Bair Hugger; correct?</p> <p>9 A. I was provided with hospitals that were</p> <p>10 using Bair Hugger and that's what I used. I don't --</p> <p>11 didn't go into the detail of the -- of what was used</p> <p>12 in these hospitals.</p> <p>13 Q. So you didn't know based on those documents</p> <p>14 because they didn't specify whether or not those</p> <p>15 hospitals also used other devices.</p> <p>16 A. The documents did not specify. The</p> <p>17 documents --</p> <p>18 The indication that I had was that they</p> <p>19 used -- were using Bair Hugger.</p> <p>20 Q. Are you aware that some hospitals in the NHS</p> <p>21 used both Bair Huggers and conductive warmers?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, lack of foundation, assumes facts not in</p> <p>24 evidence.</p> <p>25 A. I have not seen any data that -- that breaks</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. Did you ask 3M for more information as to</p> <p>2 whether the data that they provided, which showed that</p> <p>3 some hospitals used the Bair Huggers, may also use</p> <p>4 other devices?</p> <p>5 A. I didn't -- was not provided with any data</p> <p>6 that indicated whether other devices were used by</p> <p>7 any --</p> <p>8 Q. Did you ask them whether or not --</p> <p>9 A. Well my understanding was when it was given,</p> <p>10 that those were using the Bair Hugger.</p> <p>11 Q. And you also just testified that it may very</p> <p>12 well be that they used other devices as well; correct?</p> <p>13 A. Well I don't --</p> <p>14 I didn't compare this to the list of all</p> <p>15 hospitals in the U.K.</p> <p>16 Q. Understood. But --</p> <p>17 A. So there may be hospitals outside of this</p> <p>18 data set, and there is an issue -- issue there that I</p> <p>19 cannot -- you know, cannot speak to.</p> <p>20 Q. But you recognize that other hospitals may</p> <p>21 use --</p> <p>22 A. It's possible.</p> <p>23 Q. -- devices in addition to the Bair Hugger.</p> <p>24 A. Sure. Yes.</p> <p>25 Q. And if that is true, the statistic of an</p>

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<p style="text-align: right;">Page 242</p> <p>1 infection rate of .6 from 2010 to 2015 may or may not 2 be attributable just to the Bair Hugger. 3 A. It depends on the act -- the degree to 4 which, which is -- is true, that they only used one 5 device and not the other. 6 Q. And you don't know that degree of accuracy. 7 A. I don't know the degree of accuracy. That 8 was not part of the data that I was provided as -- as 9 to measure. 10 Q. And you didn't ask for that data. 11 A. No. 12 Q. To the extent you argue that the infection 13 rate from 2010 to 2015 was .6 percent, are you aware 14 that there was a significant decrease in deep joint 15 infections in the NHS from 2013 to 2015? 16 A. I didn't have data specifically relating to 17 these. 18 Q. So you did not review the Public Health of 19 England's report entitled "Surveillance of Surgical 20 Site Infections in NHS Hospitals in England?" 21 A. No. 22 Q. Okay. So you're not aware that, according 23 to that document, there was a significant decrease in 24 the years of 2013 to '14 and 2014 to '15 and 2014 to 25 fif -- '15 -- I said that twice -- but from 2013 to</p>	<p style="text-align: right;">Page 244</p> <p>1 Q. Okay. You also argue that there is no 2 reason provided for why the McGovern authors started 3 the study period on July 1st, 2008; correct? 4 A. Yes. 5 Q. And you go on to argue that had the authors 6 began the study just one month earlier, the data would 7 show a change from significance to non-significance; 8 correct? 9 A. Using the chi-square test, yes. 10 Q. And again you assume, based on that 11 calculation as provided in the figures attached to 12 your report, that you had complete information with 13 respect to infection data prior to July 1st, 2008; 14 correct? 15 A. That's based on the Albright 10 -- Exhibit 16 10 data, yeah. 17 Q. And we've discussed that document. 18 A. Yes, uh-huh. 19 Q. And are you aware that Mr. Reed -- Dr. Reed 20 has testified that there was not full surveillance at 21 Wansbeck Hospital prior to July 1st, 2008? 22 A. Yes. I'm aware that he said that, yeah. 23 Q. Are you aware that he said that if one were 24 to look at data prior to the study period, there would 25 be, quote, big gaps in the period, end quote?</p>
<p style="text-align: right;">Page 243</p> <p>1 2015. 2 A. Yeah. I -- I mean maybe it was, or these -- 3 That decrease changing the accuracy would go 4 to the reporting, as you said, that Dr. Reed reported 5 that it's notoriously inaccurately reported, so maybe, 6 yeah. I don't know what the magnitude of the 7 difference is. I -- I -- 8 To answer your question specifically, I did 9 not review that document. 10 Q. Okay. To the extent that you argue that the 11 infection rate was .6 percent from 2010 to 2015, what 12 is your basis for determining that it is related to 13 the Bair Hugger as opposed to the other SSI 14 intervention practices that were incorporated in these 15 hospitals during that time? 16 MR. GORDON: Objection, object to the form, 17 and also misconstrues his testimony. 18 A. You know, I -- it's -- I mean I -- 19 It's just using the values that they're -- 20 they're using. The data that we had -- that I had 21 was -- did not provide information other than, as -- 22 as I've said, that these were hospitals using Bair 23 Hugger and this was their infection rate. I don't 24 have information on -- on what other SSI methods they 25 might happen to have been using.</p>	<p style="text-align: right;">Page 245</p> <p>1 A. That's -- that's -- that's what he reported. 2 Q. Are you aware that Dr. Reed also testified 3 that to rely on data prior to July 1st, 2008 would be, 4 quote, very unreliable, end quote? 5 A. That's what he reported. 6 I mean related to this, I mean there's a -- 7 there was a review of -- of the procedures that they 8 were using that's referred to in one of the other 9 papers -- 10 What is the author? Starts with a G. 11 Gissell? 12 Q. Gillson. 13 A. Gillson. Thank you. 14 -- that this was all not reviewed until 15 December, so I'm not sure where -- what Reed is 16 referring to. 17 Q. So you don't believe Dr. Reed's testimony 18 that full surveillance began on Septem -- on July 1st, 19 2008. 20 A. Well he's -- he's depending on his 21 recollection, -- 22 Q. Okay. 23 A. -- I assume, in his deposition. 24 Q. Uh-huh. 25 A. And I mean that's what he's -- what -- what</p>

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<p style="text-align: right;">Page 246</p> <p>1 he said in his -- in his deposition; however, that 2 seems to not correspond in a peer-reviewed paper what 3 was said about when this was all reviewed. 4 Q. So is your statement that in the Gillson 5 article the authors there represented that the full 6 surveillance began in December of 2008? 7 A. It was reviewed in December. 8 Q. Reviewed in December. But you have no 9 knowledge -- 10 A. I don't -- 11 Q. -- as to whether -- 12 A. It doesn't say when it was implemented, -- 13 Q. Okay. 14 A. -- but that would imply, if it was not 15 reviewed until December, that it would have been not 16 implemented until maybe January. Right? I mean if 17 it's not -- 18 Q. January '09? 19 A. '09. Yeah. 20 Q. Okay. So if full surveillance wasn't 21 implemented until January '09, -- 22 A. Yes. 23 Q. -- you're relying on data from July -- prior 24 to July 2008. 25 A. These were the data that were -- were</p>	<p style="text-align: right;">Page 248</p> <p>1 reporting appropriately. 2 Q. So if this document from the NHS says that 3 since July 2008 hospitals are required to have sys -- 4 systems in place to identify patients who are included 5 in the surveillance and later admitted to hospitals 6 with an SSI, would that clarify any doubt as to when 7 full surveillance began in the NHS? 8 MR. GORDON: Object to the form of the 9 question, lack of foundation. 10 A. Well there is -- 11 I mean you're -- you're raising questions 12 about how accurate the data were recorded, but I mean 13 all of these change -- changes took place during the 14 McGovern study. 15 Q. If Mr. Reed's testimony is true -- if Dr. 16 Reed's testimony is true -- 17 MR. SACCHET: I just said "mister," 18 but I -- 19 (Discussion off the stenographic record.) 20 Q. Okay. If Mr. Reed's testimony is that full 21 surveillance began on July 1st, 2008, that is the 22 start of the Bair Hugger period in the McGovern study; 23 correct? 24 A. That's -- 25 According to his deposition, that -- that's</p>
<p style="text-align: right;">Page 247</p> <p>1 provided. These were the data that I had available to 2 me. 3 Q. But -- 4 So I just want to be clear. Based on what 5 you just said, it's either possible that full 6 surveillance began on July 1st, 2008 or -- 7 A. Yes. 8 Q. -- perhaps even January 1st, 2009, -- 9 A. So what -- 10 Yeah. 11 Q. -- but you nonetheless constructed your 12 model on data that was prior to that time; correct? 13 A. That's -- that's right. 14 Q. And that data -- 15 A. And -- 16 Q. -- may or may not be complete. 17 A. And -- 18 Q. Answer the question, please. 19 A. Well according to Reed's testimony, if 20 Reed's correct, if -- if -- if this is correct, that 21 might be true. 22 Q. Okay. 23 A. The other thing that's true, then, if that's 24 what in fact took place, is that six months -- or 25 whatever it is -- six months or so of McGovern is not</p>	<p style="text-align: right;">Page 249</p> <p>1 what it corresponds to, yes. 2 Q. And you have no evidence to doubt that, do 3 you, Professor Holford? 4 MR. GORDON: Object to the form of the 5 question. 6 A. I mean the evidence to doubt it is that 7 seems to be somewhat contradictory to what Gillson 8 says, but I mean I -- I'm not going to -- you know, I 9 don't -- I'm -- I'm -- 10 I'll -- I'll take -- I'll take him at his 11 word. 12 Q. Okay. And taking him at his word, full 13 surveillance starts on July 1st, 2008. 14 A. That's what he said. 15 Q. Yes. 16 (Exhibit 24 was marked for 17 identification.) 18 BY MR. SACCHET: 19 Q. Professor Holford, is this the Gillson 20 article that you are referring to that was cited in 21 your report? 22 A. Is this it? I don't think it is. 23 Q. Okay. Let me -- 24 A. I -- let's see. 25 MR. SACCHET: I may have marked the wrong</p>

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<p style="text-align: right;">Page 250</p> <p>1 document, professor. Is it -- I just --</p> <p>2 I'll shortcut this because I think I might</p> <p>3 have. Is the first line of the document you're</p> <p>4 looking at actually from Brister, not Gillson?</p> <p>5 MR. GORDON: Yeah.</p> <p>6 MR. SACCHET: I may have given you the wrong</p> <p>7 one.</p> <p>8 MR. GORDON: That's what you want to give</p> <p>9 him.</p> <p>10 MR. SACCHET: Okay.</p> <p>11 THE WITNESS: Yeah. I think this is one of</p> <p>12 the ones that --</p> <p>13 MR. SACCHET: Yeah. That's my fault.</p> <p>14 THE WITNESS: Yeah. It's strange, because</p> <p>15 the author is not -- doesn't appear on it, which is</p> <p>16 kind of a --</p> <p>17 MR. SACCHET: The author is there on the</p> <p>18 top, it's just --</p> <p>19 It's my fault.</p> <p>20 THE WITNESS: Okay. Yeah. It was hard to</p> <p>21 find the author on this one, that's what -- yeah.</p> <p>22 Anyway --</p> <p>23 MR. GORDON: This is al --</p> <p>24 This Exhibit 24 is on his list of</p> <p>25 references, it's just --</p>	<p style="text-align: right;">Page 252</p> <p>1 A. I've got a --</p> <p>2 Q. -- one thing that might be helpful is you</p> <p>3 would agree, wouldn't you, that this particular</p> <p>4 document relates to Northumbria Healthcare; correct?</p> <p>5 A. That includes Wansbeck, yeah.</p> <p>6 Q. But it's not specific to Wansbeck; correct?</p> <p>7 A. That -- that's correct.</p> <p>8 Q. So even if, for the sake of argument, this</p> <p>9 document said something to the effect that there was a</p> <p>10 different time in which full surveillance occurred,</p> <p>11 that may or may not be specific to Wansbeck.</p> <p>12 A. Well I assume it would include Wansbeck.</p> <p>13 I -- I don't know how they operate, but -- yeah.</p> <p>14 Q. It's possible that Wansbeck may have been</p> <p>15 ahead of the curve with respect to what NHS did as a</p> <p>16 trust; correct?</p> <p>17 A. I -- I guess that's possible.</p> <p>18 Q. Okay. So even if there's a date in this</p> <p>19 document that's specific to NHS, it does not</p> <p>20 contradict Mr. Reed's testimony.</p> <p>21 A. Not necessarily.</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, --</p> <p>24 A. Well --</p> <p>25 MR. GORDON: -- assumes facts not in</p>
<p style="text-align: right;">Page 251</p> <p>1 MR. SACCHET: Yeah, it's the Brister</p> <p>2 article.</p> <p>3 THE WITNESS: Yeah, okay. Yeah. I didn't</p> <p>4 think this was Gillson, that's all. See, Gillson</p> <p>5 is -- where are we -- same journal, 2014, June '17.</p> <p>6 Is that true? That was --</p> <p>7 Oh, no. It was published in 21 -- 2011.</p> <p>8 Yeah, that's Brister.</p> <p>9 MR. SACCHET: Yeah.</p> <p>10 THE WITNESS: Yeah.</p> <p>11 (Exhibit 25 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Is this the Gillson article that you were</p> <p>15 referring to?</p> <p>16 A. Yes, it is.</p> <p>17 Q. Okay.</p> <p>18 A. Yes.</p> <p>19 Q. Can you point me to any particular statement</p> <p>20 in this article where there's information that</p> <p>21 contradicts Mr. Reed's testimony?</p> <p>22 A. Oh. There's a figure somewhere in there,</p> <p>23 which is practically illegible in this copy --</p> <p>24 Q. I don't want to spend tons of time on this,</p> <p>25 professor, but --</p>	<p style="text-align: right;">Page 253</p> <p>1 evidence.</p> <p>2 A. --it may or may not. I don't know.</p> <p>3 Q. Well let's just do an example. If this</p> <p>4 document said that the NHS implemented full-scale</p> <p>5 surveillance of DJI in 2015 -- which it doesn't, but</p> <p>6 for the sake of argument assume that to be true --</p> <p>7 A. Yeah. Well it --</p> <p>8 MR. GORDON: Wait, wait.</p> <p>9 A. It's -- it's talking about --</p> <p>10 MR. GORDON: Wait, wait. Is there --</p> <p>11 I don't think he was done with his question.</p> <p>12 MR. SACCHET: I'm not. Thank you.</p> <p>13 Q. -- even if there was such a suggestion in</p> <p>14 this paper, that does not preclude the possibility</p> <p>15 that Wansbeck started full-scale surveillance for</p> <p>16 itself on July 1st, 2008.</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, also assumes facts not in evidence.</p> <p>19 A. I -- I don't --</p> <p>20 This is dealing with, as I understand it, as</p> <p>21 I recall, Northumbria, --</p> <p>22 Q. Yeah.</p> <p>23 A. -- which includes, what, about three</p> <p>24 hospitals I think.</p> <p>25 Q. Three hospitals, that's correct.</p>

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<p style="text-align: right;">Page 254</p> <p>1 A. And one of them being Wansbeck. 2 Q. That's correct. 3 A. And so if they're making a policy with -- 4 with regard to their group of hospitals, then I 5 would -- 6 Was what you're suggesting is Wansbeck is 7 going outside of their -- 8 Q. Ahead of the curve. 9 A. It's -- I guess it's conceivable. 10 Q. That's how law works with respect to the 11 federal government and states; correct? States can 12 implement rights that are more progressive than what 13 the federal government has promulgated; correct? 14 A. They -- they can. Whether hospitals -- 15 hospital groups function that much, I -- I just don't 16 know that much about the hospitals in -- in -- in the 17 U.K. 18 Q. Okay. 19 A. I mean this took place in, what was it, 20 2008, '10, in that area, and when was Reed's 21 testimony? 22 Q. His deposition testimony? 23 A. His deposi -- yeah. 24 Q. 2016. 25 A. '16. So I mean he's recalling things, you</p>	<p style="text-align: right;">Page 256</p> <p>1 A. Well these -- these data -- I mean that -- 2 The Albrecht 10, as I understand it, was not 3 the routine way in which a lot of these data were 4 collected, that they had to go back to the hospitals 5 and add a lot of the variables that they did, and so 6 in doing that, well, they went back to -- what was 7 it -- 8 Q. Sometime in 2007. 9 A. -- sometime in 2007, whatever it was, well 10 before Mr. July 2008. 11 Q. But based on Mr. Reed's testimony, you do 12 not know -- 13 A. Based on the testimony -- 14 Q. -- whether it was a complete data set prior 15 to July 1st, 2008. You don't know. 16 A. Well was he talking about Albrecht 10? I 17 don't know. 18 Q. I'm talking about reconstruct -- 19 A. I know what you're talking about, -- 20 Q. Yeah. 21 A. -- but I'm not sure what Reed is talking 22 about. 23 Q. Talking about Wansbeck Hospital; correct? 24 A. Okay. But he -- 25 MR. GORDON: Object to the form of the</p>
<p style="text-align: right;">Page 255</p> <p>1 know, what, seven or eight years ago. It seems 2 possible that he misremem -- didn't remember it quite 3 right. 4 Q. Well this document was published in 2014; 5 correct? October for that matter. 6 A. Yeah, but -- well it -- this is a -- 7 Gillson and Lowdon were writing this in the 8 leisure of their office. They weren't under 9 deposi -- under pressure of being under a 10 deposition -- 11 Q. Okay. 12 A. --- and having to come up with answers off 13 the top of your head. 14 Q. Okay. So let's just -- 15 I think we need to cut to it. There's 16 nothing in this doc -- document that necessarily 17 contradicts Mr. Reed's testimony. 18 A. It may not. 19 Q. It may not. 20 A. Yeah. It -- it -- 21 Yeah, it may or may not. I -- 22 Q. Is there any other evidence you relied on, 23 apart from that document, to surmise that there was 24 full reporting before July 1st, 2008 or after July 25 1st, 2008?</p>	<p style="text-align: right;">Page 257</p> <p>1 question. 2 A. Was he talking about the data in Albrecht 3 10? I just -- I don't remember, frankly. 4 Q. Okay. Did you make any inquiry separate and 5 apart from the Gillson document about when full 6 reporting began at Wansbeck? 7 A. No. 8 Q. And you didn't ask 3M for any documents on 9 the subject matter. 10 A. No. 11 Q. And they provided no such documents on the 12 subject matter. 13 A. Not of when the -- on the -- on those 14 procedures, yeah. 15 Q. Okay. 16 A. They didn't. 17 Q. So your opinion as to the table that you 18 provided is based on Albrecht Exhibit 10 and that's 19 it. 20 A. That's right. 21 Q. Okay. With respect to Fig. 2, you provide 22 time trend data and there is a moving average line 23 which is the solid blue line; correct? 24 A. Yes. 25 Q. And that line -- or that data also begins in</p>

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<p style="text-align: right;">Page 258</p> <p>1 2007; correct?</p> <p>2 A. That's right.</p> <p>3 Q. And it begins on September 1st, 2007, which</p> <p>4 is approximately 10 months before the McGovern study</p> <p>5 period; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And that data also depends on Albrecht</p> <p>8 Exhibit 10; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And with respect to the first spike in this</p> <p>11 figure, if you took away the data prior to July 1st,</p> <p>12 2008, wouldn't be much of a spike; correct?</p> <p>13 A. Well it's sort of -- yeah. In the earlier</p> <p>14 data there was really very little going on, the rates</p> <p>15 were very, very low. Bair Hugger was being used, as I</p> <p>16 understand it, but the infection rates were extremely</p> <p>17 low.</p> <p>18 Q. And to the extent that there was incomplete</p> <p>19 data prior to July 2007, that would explain the low</p> <p>20 rates; correct?</p> <p>21 MR. GORDON: Objection, assumes facts not in</p> <p>22 evidence.</p> <p>23 A. I mean the reason there were no -- there</p> <p>24 were very few in -- infections -- I mean I don't -- I</p> <p>25 don't know. There were very few reported in the -- in</p>	<p style="text-align: right;">Page 260</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay.</p> <p>4 MR. GORDON: Well --</p> <p>5 Q. The broken blue line --</p> <p>6 A. Well it depends on --</p> <p>7 I mean the four also comes from the -- from</p> <p>8 the deposition by Reed where he reports that there was</p> <p>9 one more in -- one more infection for --</p> <p>10 Well, he reports one more in each group.</p> <p>11 Q. Okay. But you don't ever, aside from</p> <p>12 footnote one, assume that there is one more infection</p> <p>13 in the Bair Hugger period; correct?</p> <p>14 MR. GORDON: Object to the --</p> <p>15 A. That's --</p> <p>16 Well I -- I mean I used -- used Exhibit 10.</p> <p>17 Q. Yes. But you just --</p> <p>18 A. I mean, again, we've been talking about</p> <p>19 Reed --</p> <p>20 Q. Uh-huh.</p> <p>21 A. -- and it seems quite possible that Reed</p> <p>22 was, you know, retrospectively recalling what took</p> <p>23 place, --</p> <p>24 Q. Uh-huh. And Reed --</p> <p>25 A. -- and so he said there was one more.</p>
<p style="text-align: right;">Page 259</p> <p>1 the data file.</p> <p>2 Q. In Albrecht Exhibit 10.</p> <p>3 A. Yes.</p> <p>4 Q. And the green line is the constant average</p> <p>5 of deep joint infection in the Bair Hugger period and</p> <p>6 the Hot Dog period; correct?</p> <p>7 A. That's right.</p> <p>8 Q. And that is also based on Albrecht Exhibit</p> <p>9 10; correct?</p> <p>10 A. Yes.</p> <p>11 Q. So instead of an infection rate of 3.0, your</p> <p>12 infection rate with respect to the Bair Hugger period</p> <p>13 is 2.91.</p> <p>14 A. Something like that.</p> <p>15 Q. Okay.</p> <p>16 A. Looks about right.</p> <p>17 Q. And the Hot Dog rate, instead of being .8</p> <p>18 percent, is 1.08 percent; correct?</p> <p>19 A. That sounds about right, and it looks about</p> <p>20 right from the -- from the graph.</p> <p>21 Q. And that's based on using four Hot Dog</p> <p>22 infections instead of three Hot Dog infections;</p> <p>23 correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And that derives from Albrecht Exhibit 10;</p>	<p style="text-align: right;">Page 261</p> <p>1 Q. Uh-huh.</p> <p>2 A. Well, I wouldn't accuse him of lying if</p> <p>3 there in fact was one more in one group and one less</p> <p>4 in the other.</p> <p>5 Q. Okay. If you wouldn't accuse him of lying,</p> <p>6 you didn't rely on those numbers at any place in your</p> <p>7 report other than footnote one; correct?</p> <p>8 A. Other than footnote -- footnote one, yeah.</p> <p>9 Footnote one is basically where I --</p> <p>10 Q. That's the full extent.</p> <p>11 A. That's right. I took -- I took -- took him</p> <p>12 at his word and --</p> <p>13 Q. Okay.</p> <p>14 A. -- used those values.</p> <p>15 Q. So with respect to the statement you made</p> <p>16 prior to that, you're relying on Reed with respect to</p> <p>17 four Hot Dog infections but not 32 or 33 Bair Hugger</p> <p>18 infections, only 31 Bair Hugger infections.</p> <p>19 A. Well the numbers -- the numbers that were</p> <p>20 used in that tabulation were the numbers that I got</p> <p>21 from -- from the -- from Albright 10 --</p> <p>22 Q. Yeah.</p> <p>23 A. -- and --</p> <p>24 Q. Which is inconsistent with Reed's testimony;</p> <p>25 correct?</p>

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<p style="text-align: right;">Page 262</p> <p>1 A. It's inconsistent. 2 Q. Yeah. 3 A. Yeah. It's the -- it's -- it's -- 4 I think it's the same for Hot Dog, but it's 5 inconsistent for Bair Hugger. 6 Q. Well Reed says four infections Hot Dog, 33 7 infections Bair Hugger; correct? One more in each 8 group. 9 A. That's what -- that's what he said. 10 Q. Yeah. 11 A. Yeah. 12 Q. And the -- 13 A. But -- but the tab -- but -- 14 But Albright 10 -- 15 Q. Yeah. 16 A. -- says four and 31. 17 Q. But you wouldn't assume, like you just said, 18 that Reed would be lying; right? 19 A. No. I just -- I -- I would guess that 20 he's -- that he's not remembering things. I mean as 21 we -- as you notice, he's reporting on -- he's talking 22 about something in his deposition about eight -- 23 Q. Yeah. 24 A. -- seven or eight years later, and he may 25 not remember --</p>	<p style="text-align: right;">Page 264</p> <p>1 Q. I can re -- I'll rephrase. 2 Your calculation derives from four Hot Dog 3 infections and 31 Bair Hugger infections; correct? 4 A. Yeah. Well, which derives from Albrecht 10. 5 Q. Albrecht 10. 6 A. Yes. 7 Q. And there's no reason to suspect that Reed 8 was lying. He testified that there was four Hot Dog 9 infections and 33 Bair Hugger infections, and if that 10 is true, that would change all of the calculations in 11 your report; correct? 12 A. It would change many of them. I mean 13 ideally what I would like to know is why -- what -- 14 what the correct -- 15 While Reed may not remember exactly what 16 took place, what -- what the -- what the values were, 17 I think he's -- he's suggesting that there -- there 18 was an error in the data that are published in 19 McGovern. 20 Q. And assuming that to be true, one of those 21 errors is actually there was more Bair Hugger 22 infections. 23 A. And more -- I mean he -- 24 One of the things he is conceding is that 25 there is more -- there -- there's one more Hot Dog</p>
<p style="text-align: right;">Page 263</p> <p>1 Q. Okay. 2 A. -- things quite right. 3 Q. But with respect to the four infections and 4 33 infections, that might be true, but it may not be 5 true that the start date was July 1st, 2008. 6 A. Yeah. I mean if he mis -- if he 7 misremembered one, it's possible he misremembered the 8 other as well. 9 Q. Okay. 10 A. I mean I -- I don't know. 11 Q. But you don't know. 12 A. I -- 13 No, I don't know. I don't know. If you 14 asked me what I was doing -- 15 Q. Yeah. 16 A. -- in July 2008, I don't think I could tell 17 you very accurately. 18 Q. Had you relied on Reed's testimony regarding 19 the four infections in the Hot Dog group and the 33 20 infections in the Bair Hugger group, all of the 21 calculations in your report would be different; 22 correct? 23 MR. GORDON: Object to the form of the 24 question, assumes facts not in evidence. 25 A. Yeah. I'm not sure what --</p>	<p style="text-align: right;">Page 265</p> <p>1 infection. 2 Q. But you took into account -- 3 A. Because there's -- because there's so few, 4 there's only three, -- 5 Q. Yeah. 6 A. -- you're going from three to four, so 7 that's a 33 percent difference, so that's having a 8 much bigger effect on your estimates of risk than the 9 change of one or two in the -- in the -- in the Bair 10 Hugger. 11 Q. But you never used that data with respect to 12 the Bair Hugger; correct? 13 MR. GORDON: Objection. 14 Q. You only used the four hundred -- or the 15 four Hot Dog infections and only used 33 Bair Hugger 16 infections in footnote one of your report; correct? 17 A. That's the only place -- that's the only 18 place I -- I change it in my report. 19 Q. Okay. 20 A. Yeah. 21 Q. Okay. 22 A. I mean ideally what I would like to know, as 23 this implies, that there is -- that -- for Albrecht 24 10, and to be consistent, I would like to get it 25 consistent with -- with Reed.</p>

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<p style="text-align: right;">Page 266</p> <p>1 Q. And you can't.</p> <p>2 A. Not as they're given.</p> <p>3 Q. Okay.</p> <p>4 A. They would have to sit down and somehow make</p> <p>5 a correction, either --</p> <p>6 Well either Reed is right or -- or Albrecht</p> <p>7 10 is -- is right on this particular question, and it</p> <p>8 would be good if -- it would be nice if I could sit</p> <p>9 down and they could correct what this -- what</p> <p>10 the -- what the -- what the discrepancy is.</p> <p>11 Q. And you --</p> <p>12 A. There is a discrepancy.</p> <p>13 Q. And you don't know.</p> <p>14 A. And I don't know why there is a discrepancy.</p> <p>15 Q. And you don't know which one it might be.</p> <p>16 A. I don't know. I mean in looking at a file</p> <p>17 that looks like a raw data set gives me at bit more</p> <p>18 confidence than someone remembering something eight</p> <p>19 years ago. But in any event, it needs -- well</p> <p>20 someone --</p> <p>21 Ideally, someone would sit down with these</p> <p>22 data and, you know, review it with the -- with the raw</p> <p>23 records and -- and -- to correct whatever -- whatever</p> <p>24 it is.</p> <p>25 Q. It could also be neither.</p>	<p style="text-align: right;">Page 268</p> <p>1 Q. A variable C is a confounder if it is</p> <p>2 related to disease and also related to exposure.</p> <p>3 A. If -- if it is related to disease and it's</p> <p>4 related to the exposure --</p> <p>5 We're not saying statistically significant;</p> <p>6 right?</p> <p>7 Q. Yeah. I'm just --</p> <p>8 Just for this definition.</p> <p>9 A. Yeah. If that --</p> <p>10 If those are true, then it is a confounder.</p> <p>11 Q. That's how you defined it in your article</p> <p>12 "Confounding in Epidemiological Studies" which was</p> <p>13 published in Biometrics; correct?</p> <p>14 A. Oh. Oh, right, right. Yeah, that's -- I --</p> <p>15 I didn't remember which -- trying to remember which</p> <p>16 article you were talking about. Yeah.</p> <p>17 Q. By Wickramaratne --</p> <p>18 A. Oh, okay.</p> <p>19 Q. -- and you.</p> <p>20 A. Not the --</p> <p>21 Okay. Yeah, yeah, yeah, yeah.</p> <p>22 Q. That's how you defined it.</p> <p>23 A. Okay.</p> <p>24 Q. And according to Dr. Borak, differently</p> <p>25 stated, a variable must be an independent risk factor</p>
<p style="text-align: right;">Page 267</p> <p>1 A. That neither one was right?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, assumes facts not in evidence, calls for</p> <p>4 speculation.</p> <p>5 Q. I mean the published data is neither one of</p> <p>6 those two. Correct?</p> <p>7 A. It's neither one of them.</p> <p>8 MR. GORDON: Same objection.</p> <p>9 Q. Right. It's -- it's neither Albrecht 10 --</p> <p>10 A. Oh, I see. Yeah.</p> <p>11 Q. -- nor Reed's testimony.</p> <p>12 A. Yeah. I mean if it's -- yeah, if you're</p> <p>13 going --</p> <p>14 Q. On the published data.</p> <p>15 A. Yeah. If the published data is -- is</p> <p>16 correct --</p> <p>17 Q. Okay.</p> <p>18 A. -- and there's -- I mean, you know, there's</p> <p>19 some doubt, obviously, but --</p> <p>20 Q. Let's move to the confounding portion of</p> <p>21 your report. And I'd like to establish a definition</p> <p>22 of "confounding," which I'll phrase as a variable C is</p> <p>23 a confounder if it is related to disease and also</p> <p>24 related to exposure. Do you agree with that?</p> <p>25 A. State that again.</p>	<p style="text-align: right;">Page 269</p> <p>1 for it to be a confounder on the outcome; correct?</p> <p>2 MR. GORDON: Well object, foundation.</p> <p>3 A. Yeah. It needs to be a risk --</p> <p>4 It needs to have an association.</p> <p>5 Q. Okay. And if there's no such association to</p> <p>6 the outcome, it's not a confounder; correct?</p> <p>7 A. That's right. I'm not eliminating it, of</p> <p>8 course.</p> <p>9 Q. Yeah. I know what you said before, but --</p> <p>10 A. Again, I'm not saying --</p> <p>11 Q. -- if there's no a priori relationship, it's</p> <p>12 not a confounder.</p> <p>13 A. Yeah. And we're taking about statis --</p> <p>14 We're not talking about statistics.</p> <p>15 Q. An a priori relationship.</p> <p>16 A. Yeah.</p> <p>17 Q. If there's an a priori --</p> <p>18 If there's not an a priori relationship</p> <p>19 between a variable and an outcome, it's not a</p> <p>20 confounding factor.</p> <p>21 A. That's right. Adjusted for the -- adjusted</p> <p>22 for each other, yeah.</p> <p>23 Q. Okay. Are you aware that thromboprophylaxes</p> <p>24 are used for reducing the risk of blood clotting?</p> <p>25 A. I -- yeah. I think so, yeah. Yeah.</p>

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<p style="text-align: right;">Page 270</p> <p>1 Q. The point of using --</p> <p>2 A. Yeah.</p> <p>3 Q. -- a thromboprophylaxis, whether it be</p> <p>4 tinzaparin or Xarelto or any other low-molecular-</p> <p>5 weight heparin, is to reduce the incidence of venous</p> <p>6 thrombosis; right?</p> <p>7 A. Okay. I'm not a clinician, but --</p> <p>8 Q. So you're not a clinician but you're</p> <p>9 assuming there's an a priori relationship between</p> <p>10 thrombo and other outcomes separate and apart from</p> <p>11 deep vein thrombosis?</p> <p>12 A. Well what you're asking for is a -- is a</p> <p>13 particular relationship, which is not --</p> <p>14 I mean there are lots of drugs that are</p> <p>15 related to more than one thing.</p> <p>16 Q. Okay.</p> <p>17 A. So the fact that that's what it is used for</p> <p>18 does not mean it does not -- does or does not have</p> <p>19 another effect.</p> <p>20 Q. Okay. Do you know how thromboprophylaxes</p> <p>21 are administered?</p> <p>22 A. No.</p> <p>23 Q. You're not aware that Xarelto is</p> <p>24 administered postoperatively.</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. It is.</p> <p>2 A. Okay. I don't --</p> <p>3 I was not aware of that. I --</p> <p>4 Q. Okay. Have you studied the record trials?</p> <p>5 A. No, I have not.</p> <p>6 Q. You're not aware that there were five</p> <p>7 randomized controlled trials that evaluated the safety</p> <p>8 of rivaroxaban, otherwise known as Xarelto, in</p> <p>9 orthopedic surgeries?</p> <p>10 A. No, I'm not familiar with that.</p> <p>11 Q. You're not aware that one of the studies</p> <p>12 concluded that the clinical efficacy and safety of</p> <p>13 rivaroxaban after elective hip and knee arthroplasty</p> <p>14 has been established in the four randomized controlled</p> <p>15 trials of the regulation of coagulation in orthopedic</p> <p>16 surgery to prevent deep vein thrombosis.</p> <p>17 A. I was not familiar with that.</p> <p>18 Q. Did you attempt to investigate whether</p> <p>19 thromboprophylaxes have been deemed to be safe in</p> <p>20 orthopedic surgeries?</p> <p>21 A. No. I was -- I was looking at -- well the</p> <p>22 same -- the evidence that -- that McGovern cited as --</p> <p>23 He was citing the -- the work that was done</p> <p>24 by -- the paper by Jensen I believe.</p> <p>25 Q. So the only basis for an a priori assumption</p>
<p style="text-align: right;">Page 271</p> <p>1 Q. You're not aware that tinzaparin is also</p> <p>2 often administered postoperatively.</p> <p>3 A. I didn't know how they were operate -- they</p> <p>4 were --</p> <p>5 Q. You didn't read that in the McGovern study?</p> <p>6 A. I probably did. I wasn't --</p> <p>7 I mean they were using it in the Jensen</p> <p>8 study, they were using it and comparing it and looking</p> <p>9 at it for an effect with -- with infections.</p> <p>10 Q. Understood. But you're aware that the</p> <p>11 McGovern study, the patients received the</p> <p>12 thromboprophylaxis postoperatively.</p> <p>13 A. Okay.</p> <p>14 Q. Okay. So the thromboprophylaxis does not</p> <p>15 add particles to the surgical site; correct?</p> <p>16 A. Presumably not.</p> <p>17 Q. It doesn't add bacteria to the surgical</p> <p>18 site; correct?</p> <p>19 A. No.</p> <p>20 Q. Xarelto is approved by The American College</p> <p>21 of Chest Physicians. Do you know that?</p> <p>22 MR. GORDON: Objection, lack of foundation.</p> <p>23 A. Xarelto is which one now?</p> <p>24 Q. Rivaroxaban.</p> <p>25 A. Rivaroxaban. Okay.</p>	<p style="text-align: right;">Page 273</p> <p>1 that the use of Xarelto is related to the outcome of</p> <p>2 interest; namely, deep joint infection, is the Jensen</p> <p>3 study?</p> <p>4 A. That was, my understanding, the basis on</p> <p>5 which they did not control for it.</p> <p>6 Q. And my question is a little different. Your</p> <p>7 basis for making an a priori assumption that Xarelto</p> <p>8 is related to the outcome of interest, which is deep</p> <p>9 joint infection, is only the Jensen study.</p> <p>10 A. That's what I was looking -- looking for.</p> <p>11 McGovern did not control for any</p> <p>12 confounding.</p> <p>13 Q. I understand. My question again, which I</p> <p>14 think you answered, is that the only piece of</p> <p>15 evidence --</p> <p>16 A. Yes.</p> <p>17 Q. -- that you considered as to whether there</p> <p>18 is an --</p> <p>19 A. I was --</p> <p>20 Q. -- a priori relationship between Xarelto and</p> <p>21 the outcome of interest, which is deep joint</p> <p>22 infection, is the Jensen study. True or false? It's</p> <p>23 a one-word answer.</p> <p>24 A. Yeah. Well I wasn't saying it was a priori.</p> <p>25 I was looking at the data --</p>

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<p style="text-align: right;">Page 274</p> <p>1 Q. Okay.</p> <p>2 A. -- to see whether or not there was an</p> <p>3 association.</p> <p>4 Q. Is that the only study that you looked at?</p> <p>5 A. Well I was using --</p> <p>6 I referred to that study because that was</p> <p>7 the study that McGovern referred to.</p> <p>8 Q. Did you look at any other studies?</p> <p>9 A. I didn't look at any other studies. I had</p> <p>10 be --</p> <p>11 The data on which the Jensen paper was --</p> <p>12 was based, I mean the design is basically the same</p> <p>13 sort of --</p> <p>14 Q. The same design as in McGovern.</p> <p>15 A. Yeah. It's the same flawed design that</p> <p>16 McGovern used, which is based on dates.</p> <p>17 Q. Okay. But my question again is did you look</p> <p>18 at any other studies?</p> <p>19 A. And so I could repeat -- I could repeat the</p> <p>20 analysis --</p> <p>21 Q. Okay. We'll get there. Trust me, we'll get</p> <p>22 there.</p> <p>23 A. -- that -- that they did using Albrecht 10.</p> <p>24 Q. Okay. So in other words, your only basis</p> <p>25 for concluding that the thromboprophylaxis may or may</p>	<p style="text-align: right;">Page 276</p> <p>1 Q. .7 ring a bell?</p> <p>2 A. .7?</p> <p>3 Q. Yeah.</p> <p>4 MR. GORDON: Maybe you should look at the</p> <p>5 article.</p> <p>6 A. Yeah. That seems high. I --</p> <p>7 Do you have the article?</p> <p>8 Q. We have marked the article as a prior</p> <p>9 exhibit, and I can tell you what it is in a moment.</p> <p>10 MR. GORDON: I'm look --</p> <p>11 Nineteen.</p> <p>12 A. Here. Oh, I'm --</p> <p>13 MR. GORDON: Exhibit 19.</p> <p>14 Q. If you turn to page 523 on the bottom right,</p> <p>15 or internal page 93, there's a section entitled</p> <p>16 "Results;" correct?</p> <p>17 Of the Jensen study.</p> <p>18 A. Do I have --</p> <p>19 Q. Oh, okay.</p> <p>20 MR. GORDON: It's Exhibit 19.</p> <p>21 Q. Exhibit 19, professor.</p> <p>22 A. Nineteen.</p> <p>23 MR. GORDON: That's it.</p> <p>24 Q. Okay. If you turn to page 523, in the</p> <p>25 bottom right-hand corner --</p>
<p style="text-align: right;">Page 275</p> <p>1 not be a confounder is based on the data from Albrecht</p> <p>2 Exhibit 10.</p> <p>3 A. Yes.</p> <p>4 Q. You conducted no investigation to determine</p> <p>5 whether the peer-reviewed public literature had</p> <p>6 determined that Xarelto was safe in orthopedic</p> <p>7 surgeries.</p> <p>8 A. No.</p> <p>9 Q. And the Jensen study, which appears to be</p> <p>10 the source that you rely on with application of</p> <p>11 Albrecht Exhibit 10, in fact found that there was not</p> <p>12 a significant difference between deep joint infection</p> <p>13 rates from the use of Xarelto compared to tinzaparin;</p> <p>14 correct?</p> <p>15 A. They did not find a statistical</p> <p>16 significance.</p> <p>17 Q. That's the scope of the question.</p> <p>18 A. That's right.</p> <p>19 Q. And the p-value wasn't even close to</p> <p>20 significant; correct?</p> <p>21 A. Yes. The p-value was --</p> <p>22 Yeah.</p> <p>23 Q. Do you know what it was?</p> <p>24 A. I think somewhere around .11 or something.</p> <p>25 I don't remember.</p>	<p style="text-align: right;">Page 277</p> <p>1 A. Okay.</p> <p>2 Q. -- on the left column is a section entitled</p> <p>3 "Results;" correct?</p> <p>4 A. Yes.</p> <p>5 Q. Do you see the third paragraph that says,</p> <p>6 "Of those...?"</p> <p>7 A. Yeah.</p> <p>8 Q. It says, "Of those patients who returned to</p> <p>9 theatre, microbiology results showed that five of the</p> <p>10 nine (55.5 percent) in group 1 had a deep infection,</p> <p>11 compared with 14 of 22 (63.6 percent) in group 2 (p</p> <p>12 equals 0.7)."</p> <p>13 A. Okay.</p> <p>14 Q. Does that refresh your recollection --</p> <p>15 MR. GORDON: Well why don't you read the</p> <p>16 rest of the section that actually talks about deep</p> <p>17 infection.</p> <p>18 THE WITNESS: Yeah.</p> <p>19 Q. "The overall rate of deep infection in group</p> <p>20 1 was one percent, compared with 2.5 percent in group</p> <p>21 2" with a p-value of .1.</p> <p>22 A. Right. So that's what I was --</p> <p>23 Q. Is that the p-value of interest or is it the</p> <p>24 .7?</p> <p>25 A. I was thinking it was --</p>

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<p style="text-align: right;">Page 278</p> <p>1 You're com -- you're comparing the deep 2 infection rate -- 3 Q. Okay. 4 A. -- between the two, and so that was the 5 comparison that I was looking at, because we were 6 looking at deep -- you know, deep infection rates in 7 McGovern. 8 And of course the definition of "deep 9 infection" is different in Jensen's paper than it is 10 in McGovern. 11 Q. It was a 30-day period whereas in -- 12 A. Thirty days -- 13 Q. -- McGovern it was a 60-day period; correct? 14 A. Exactly. 15 Q. Okay. 16 A. So there are some -- going to be some more 17 infections in -- if -- I -- I -- 18 I went on and I used the McGovern 19 definition. 20 Q. Yeah. For both arms of the study; correct? 21 A. For -- for -- that's right, for the -- for 22 Jensen. 23 Q. So there could be more infections in the 24 Bair Hugger group and there could be more infections 25 in the Hot Dog group.</p>	<p style="text-align: right;">Page 280</p> <p>1 significance, -- 2 Q. Okay. 3 A. -- so he was looking at -- 4 My understanding of Samet's statement was 5 on -- the basis of it was that they did not find that 6 it was statistically significant, -- 7 Q. Okay. 8 A. -- and on that basis he -- he dismissed it. 9 Q. To the extent that others have concluded, 10 such as Dr. Reed in his deposition, -- 11 A. Yeah. 12 Q. -- that Xarelto can be ruled out as a 13 confounding factor, do you have any basis to doubt 14 that statement? 15 A. Well I -- I mean we did -- we did the -- 16 the -- we -- 17 We talked about the reasons that a variable 18 is -- is a confounder, -- 19 Q. Yeah. 20 A. -- and as I've -- as I've said, the -- the 21 reason for it being a confounder is that there is this 22 association with the exposure and with the outcome, 23 okay, and we've stipulated that that association may 24 not be statistically significant. 25 Q. We haven't stipulated, but you said that.</p>
<p style="text-align: right;">Page 279</p> <p>1 A. Exactly. 2 Q. Okay. In addition to the Jensen study, did 3 you review the Reed study that also analyzed whether 4 there was a significant increase in deep joint 5 infection rates from the use of a low-molecular-weight 6 heparin to Xarelto? 7 A. I don't know that I looked at that much. 8 Q. It was cited by Dr. Samet; correct? 9 A. It -- it may have been. I -- I'm just not 10 re -- 11 I don't recall that one. 12 Q. I'll represent to you that it was cited 13 by -- 14 A. Okay. 15 Q. -- Dr. Samet. You did not review that 16 article? 17 A. I don't recall reviewing that article, no. 18 Q. So to the extent that Dr. Samet relied on 19 that article in concluding that the change in 20 thromboprophylaxis was not a confounding factor, you 21 have not reviewed that study and therefore cannot 22 comment on it. 23 A. Well Samet was talking about looking at 24 effects and he was basing his conclusions on the 25 conclusion of the paper, which depended on statistical</p>	<p style="text-align: right;">Page 281</p> <p>1 A. Well -- and I've -- 2 In my report I referred to the work by -- 3 the -- the textbook by -- 4 Q. Breslow and Day. 5 A. -- Breslow and Day where they in fact show 6 example -- a counterexample of where that is in fact 7 true. 8 Q. That example related to cancer and age; 9 correct? 10 A. I've forgotten what the -- what the table 11 was, but -- 12 Q. Okay. 13 A. -- it -- it doesn't really -- it doesn't 14 really matter. It was just illustrating the -- the 15 point -- 16 Q. Okay. 17 A. -- that you could have -- you could have 18 associations that are not -- that don't achieve 19 statistical significance but they do in fact behave as 20 confounders in that they change the association when 21 you adjust for them. And it can go either way, it can 22 go -- make a very weak association stronger or it can 23 make a strong association go away. 24 Q. But you had said before that it's not always 25 necessary to control for a particular variable in the</p>

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<p style="text-align: right;">Page 282</p> <p>1 event that it is not significantly related to the 2 outcome; correct? 3 A. You may need to control for it even if it is 4 not. 5 Q. The question was a little different. You've 6 said you do not need to control for a particular 7 variable in the event that there is not a significant 8 relationship between that variable and the outcome of 9 interest; correct? 10 A. No, I don't think that's quite what I -- 11 what I said. I -- the -- 12 When people are looking for confounders, 13 it's -- it's a tricky thing to look for it because 14 statistical significance is an easy thing for it to 15 sort of pop out, -- 16 Q. Uh-huh. 17 A. -- but a confounding variable is does the 18 control for this variable change the magnitude of the 19 association that you're looking for, -- 20 Q. Okay. 21 A. -- and so that's the relevant issue. 22 Q. We'll get -- we'll get there. 23 A. And that's -- and that's not what -- what -- 24 what Samet seemed to be talking about in his 25 deposition.</p>	<p style="text-align: right;">Page 284</p> <p>1 appeared in -- 2 Isn't this referring to the Wickramar -- 3 Wickramaratne -- 4 Q. Yes. 5 A. -- paper in '87? 6 Q. Okay. And you were a co-author of that 7 paper; correct? 8 A. Yes, I am. 9 Q. Okay. So as you can see on the first page 10 of text at 1309, Sander Greenland from the Department 11 of Epidemiology at UCLA -- 12 A. Yeah. 13 Q. -- provides a reader reaction; correct? 14 A. Yes. 15 Q. On page 1310, Paul Holland from Princeton, 16 New Jersey also provides a reader reaction; correct? 17 A. Yes. 18 Q. And on page 1317, Professor Mantel from 19 American University provides a review as well; 20 correct? 21 A. Yes. 22 Q. Professor Mantel is a notable statistician; 23 correct? 24 A. Yes, he is. Was. 25 Q. Oh. Okay. I didn't know that.</p>
<p style="text-align: right;">Page 283</p> <p>1 MR. SACCHET: Okay. We'll get to the change 2 in relative risk in a minute, but first I'd like you 3 to, in just a moment, return -- turn your attention to 4 what will be marked as Exhibit -- 5 THE REPORTER: Twenty-six. 6 MR. SACCHET: -- 26. 7 (Exhibit 26 was marked for 8 identification.) 9 BY MR. SACCHET: 10 Q. Is this a document regarding reader 11 reactions to your article entitled "Confounding in 12 Epidemiologic Studies?" Which you can see on page 13 1309, the first page of actual text of the document, 14 on the title. First page of text after the title 15 page. 16 A. Oh, this is -- okay. 17 Q. Have you seen this document before? 18 A. Yes, I have. 19 Q. Okay. And you indeed published an article 20 called "Confounding in Epidemiologic Studies;" 21 correct, in 1989 -- 22 A. Yes. 23 Q. -- in Biometrics? 24 A. Nineteen -- 25 Well I think this is referring -- this</p>	<p style="text-align: right;">Page 285</p> <p>1 And on page 1319 you provide a response. 2 A. Yes. 3 Q. And if you go to the paragraph on 1319 4 beginning with "Mantel," do you see it says "Mantel 5 raises...?" 6 A. Yeah. 7 Q. And it says, "Mantel raises the important 8 question often facing the applied statistician of what 9 to do when faced with the analysis or design of a 10 particular study." Do you see that? 11 A. Yes. 12 Q. I'm going to skip the next sentence and then 13 say, "Reasons given by Mantel for covariate adjustment 14 are '...to reduce bias and to increase precision.' 15 The particular example described by Mantel involves 16 age as a potential confounder for cancer, a situation 17 in which there is no question of whether there is in 18 fact association. However, in other situations, one 19 must decide whether to adjust on an empirical basis, 20 and in these instances it was not always obvious how 21 one should behave." 22 That's what you wrote; correct? 23 A. Yes. 24 Q. You then say, "Statistical significance is 25 not always the best guide as to which variables are</p>

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<p style="text-align: right;">Page 286</p> <p>1 confounders by any reasonable criterion, as was 2 elegantly pointed out in an example given by Breslow 3 and Day;" correct? 4 A. Yes. 5 Q. Why didn't you say it never is? 6 A. Well it could be. 7 Q. So in the event that there is not 8 statistical significance between two variables, there 9 may be no need to control as to whether that variable 10 is a confounder? 11 A. Well you could have an association that is 12 not statistically significant but it is important to 13 control because it -- because your estimate of 14 association is biased if you don't control it. 15 Q. But you may also have a situation in which 16 the variable is non-significant to an outcome and you 17 shouldn't control; correct? 18 A. No. It -- it has nothing to -- it's -- 19 the -- 20 The point is -- the point I was making 21 before is that -- is are -- is that statistical 22 significance is not necessarily the criteria you 23 should be looking at. 24 Q. For confounding. 25 A. For confounding. You could have</p>	<p style="text-align: right;">Page 288</p> <p>1 A. Uh-huh. 2 Q. Okay. So the bottom line is whether or not 3 something is significant, you should look at whether 4 the odds ratio changes based on the uncontrolled 5 calculation and the controlled calculation; correct? 6 A. Yes. 7 Q. And in this instance you applied McGovern 10 8 using the Jensen time periods and found that the odds 9 ratio was 2.16; correct? 10 A. Something like that. 11 Q. Is that true? 12 A. I'd have to look it up. 13 Q. Page six. 14 A. "In this case the results are" blah, blah, 15 blah. 16 2.168. I'm sorry. Okay. 17 Q. Okay. 18 A. Yeah. 19 Q. So controlling for tinzaparin -- 20 A. Yeah. 21 Q. -- in the Bair Hugger period compared to the 22 Hot Dog period, based on Albrecht 10, yielded an odds 23 ratio of 2.16; correct? 24 A. That's right. 25 Q. And the odds ratio that you calculated when</p>
<p style="text-align: right;">Page 287</p> <p>1 assoc -- I mean it's not -- it could -- 2 The reason it's not statistically 3 significant could be that there is no association, 4 okay, and that's in fact the criteria that -- that -- 5 that -- that's what's needed for there to be -- 6 Well, if there is no association, then it -- 7 then there is no confounding. 8 Q. Okay. 9 A. But there could be an association, it's just 10 that that association -- you don't have enough power 11 to -- to determine if that association -- for that 12 association to be statistically significant. 13 Q. Okay. 14 A. And so in that case, you shouldn't make your 15 choice based on the statistical significance but 16 whether or not it actually does make a change in 17 the -- in the effect. 18 Q. Okay. And that's what you mean when you go 19 on to say, "In this instance, the potential confounder 20 was not significantly associated with disease, and yet 21 the inference on the disease factor association was 22 quite different depending on whether one controlled 23 for the confounding variable in the analysis." 24 A. Yes. 25 Q. Correct?</p>	<p style="text-align: right;">Page 289</p> <p>1 you used Albrecht 10, based on the uncontrolled 2 calculation, was 2.76; correct? 3 A. That's correct. 4 Q. The decrease in the odds ratio is .6; 5 correct? 6 A. That's right. 7 Q. So that would be at best the magnitude of 8 the degree of confounding if there is any confounding, 9 correct, based on your calculation? 10 A. Yeah. Well that -- that -- that change 11 would be a change due to controlling for -- 12 controlling for use -- use of this -- of -- of this -- 13 of this treatment, whatever that corresponds to. 14 Q. But I want to be clear that the change is .6 15 in the odds ratio; correct? 16 A. That's right. That's right. 17 Q. In your response to Mantel you say that the 18 inference on the disease factor association was quite 19 different when one controlled for age with respect to 20 cancer; correct? 21 A. It depended -- 22 I don't know what the example was here. 23 Q. Okay. Would you -- 24 A. Whatever it is. 25 Q. -- view a change of .6 to be quite</p>

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<p style="text-align: right;">Page 290</p> <p>1 different?</p> <p>2 A. I'd say it's a fair -- fair difference, yes.</p> <p>3 Q. Okay.</p> <p>4 A. So 2. -- 2.76, yeah, I mean that's --</p> <p>5 it's --</p> <p>6 Q. Approximately 20 percent.</p> <p>7 A. Oh, it's more than 26 percent; isn't it?</p> <p>8 It's --</p> <p>9 Q. I don't think so.</p> <p>10 A. -- two --</p> <p>11 Q. .6 --</p> <p>12 A. -- point --</p> <p>13 Q. -- on 2.76?</p> <p>14 A. Well the 2.76, that's a -- an increase of</p> <p>15 1.76.</p> <p>16 Q. From 2.76 to 2.16 is a difference of .6.</p> <p>17 A. Right.</p> <p>18 Q. Okay.</p> <p>19 A. And so if there's no association, the odds</p> <p>20 ratio is -- is -- is one.</p> <p>21 Q. You're getting that from controlling both --</p> <p>22 A. If there's no -- no association, you're</p> <p>23 looking at --</p> <p>24 Q. Correct.</p> <p>25 A. -- the ratio of two incidence rates.</p>	<p style="text-align: right;">Page 292</p> <p>1 above. I mean look at the confidence limits.</p> <p>2 Q. Of your calculation?</p> <p>3 A. .7 --</p> <p>4 After you control for it.</p> <p>5 Q. Yes.</p> <p>6 A. .73 to 8. --</p> <p>7 I mean it's still --</p> <p>8 Q. It's --</p> <p>9 A. The estimate of what the effect is is not</p> <p>10 very precise I would say.</p> <p>11 Q. It's a third of the size of your Jensen</p> <p>12 reanalysis; is it not? Your Jensen reanalysis has as</p> <p>13 25-point confidence interval.</p> <p>14 A. The 25, that's --</p> <p>15 Q. One to 25.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence.</p> <p>18 A. Yeah. I -- you're looking at --</p> <p>19 I mean those are not a fair comparison. I</p> <p>20 mean --</p> <p>21 Q. Why not?</p> <p>22 A. I mean both of them are very poor estimates.</p> <p>23 Q. Yours is three times the size --</p> <p>24 A. Well you're looking at the range.</p> <p>25 Q. -- of this.</p>
<p style="text-align: right;">Page 291</p> <p>1 Q. This odds -- this odds ratio is still above</p> <p>2 2.0 --</p> <p>3 A. It is.</p> <p>4 Q. -- when controlling for the</p> <p>5 thromboprophylaxis; correct?</p> <p>6 A. That's right.</p> <p>7 Q. There is still a doubling of the risk even</p> <p>8 when controlling for the thromboprophylaxis; correct?</p> <p>9 A. That's right. So --</p> <p>10 Q. Okay.</p> <p>11 A. -- if you --</p> <p>12 You're looking at a difference at -- at the</p> <p>13 change above one, --</p> <p>14 Q. Okay.</p> <p>15 A. -- not -- not zero.</p> <p>16 Q. But you would still agree that the --</p> <p>17 A. It's a fairly big chart -- change.</p> <p>18 Q. -- the change --</p> <p>19 The controlled thromboprophylaxis OR is</p> <p>20 still above 2.0.</p> <p>21 A. It is, yes.</p> <p>22 Q. And it --</p> <p>23 That means it's still a doubling of the risk</p> <p>24 even when the thrombo --</p> <p>25 A. But the point -- the point estimate is</p>	<p style="text-align: right;">Page 293</p> <p>1 A. Remember, I said, you know, the -- when you</p> <p>2 construct a confidence interval on an odds ratio, you</p> <p>3 generally do it on the log transformation, --</p> <p>4 Q. Okay.</p> <p>5 A. -- and so once you threw it -- do it in the</p> <p>6 log, you have to look at it in the log scale.</p> <p>7 Q. Okay. You would agree, nonetheless, that</p> <p>8 the odds -- that the confidence interval you</p> <p>9 calculated based on the Jensen reanalysis is larger</p> <p>10 than the confidence interval of both the McGovern</p> <p>11 study and the confidence interval that you report when</p> <p>12 controlling for the thromboprophylaxis.</p> <p>13 A. The range of the two would be greater, yes,</p> <p>14 the range of the two would be greater, but a big part</p> <p>15 of that reason for the change in the range, the</p> <p>16 arithmetic difference in that range, is because the</p> <p>17 odds ration is much smaller. In the other example in</p> <p>18 the -- in the -- from the -- from the Jensen</p> <p>19 comparison, the odds ratio was 4.77.</p> <p>20 Q. Okay.</p> <p>21 A. So that's more than twice --</p> <p>22 Q. Okay.</p> <p>23 A. -- what the odds ratio is here.</p> <p>24 Q. Your odds ratio is more than three times the</p> <p>25 ev -- the confidence interval here. Your confidence</p>

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<p style="text-align: right;">Page 294</p> <p>1 interval is three times the size of the confidence 2 interval even though the odds ratio here is half the 3 amount of the odds ratio you reported -- 4 A. Yes. Okay. 5 Q. -- in the Jensen reanalysis. 6 A. Okay. 7 Q. Okay. 8 A. So I don't -- I don't -- I don't understand 9 what your point is. But -- 10 Q. My point is that it's clear that the Jensen 11 reanalysis has more variability than does your 12 calculation of the 2.16 odds ratio -- 13 A. The difference between the high and low -- 14 Q. -- when controlling for the 15 thromboprophylaxis; correct? 16 A. The difference be -- the -- the -- 17 The difference between the high and the low 18 of the confidence interval is greater on that one 19 than -- is -- is diff -- quite different between those 20 two. I agree to that. 21 Q. It's greater. 22 A. It's greater. I agree with that. 23 Q. Thank you. 24 As to the Jensen reanalysis, have you 25 published your reanalysis of the Jensen study?</p>	<p style="text-align: right;">Page 296</p> <p>1 A. I'm not. 2 Q. You don't know why they changed back to 3 tinzaparin. 4 A. No, I -- no, I don't. I don't know if this 5 is the basis of it or not. 6 Q. Okay. 7 A. But I mean this was the ba -- 8 It was Jensen's paper that -- that McGovern 9 is quoting, right, -- 10 Q. Uh-huh. 11 A. -- as the -- as for saying why it's not a 12 confounder? 13 Q. And the Jensen -- 14 A. And while the Jensen paper is not -- not 15 statistically significant, -- 16 Q. Uh-huh. 17 A. -- they nevertheless changed the policy -- 18 changed the regimen that they were using at Wansbeck. 19 Q. Okay. But you don't know why they did. 20 A. No, I don't. 21 Q. Okay. 22 A. I find it interesting. 23 Q. Did you ask anyone why they changed from 24 tinzaparin to Xarelto and back to tinzaparin? 25 A. No.</p>
<p style="text-align: right;">Page 295</p> <p>1 A. No. 2 Q. So you haven't reviewed any published 3 literature regarding the safety of Xarelto with 4 respect to deep joint infection. 5 MR. GORDON: Objection, asked and answered. 6 A. No, I've -- 7 Q. Are you going to publish it? 8 A. No. 9 Q. So there is no published literature that you 10 are aware of that suggests a relationship between the 11 variable of a thromboprophylaxis on the outcome of 12 deep joint infection. 13 A. I don't know of any. 14 Q. Okay. If we could, let me show you another 15 document. 16 A. I mean it is interesting that they in 17 fact -- they seem to have not -- 18 They went -- they went back to using the -- 19 using the treatment they were originally using even 20 though the Jensen paper did not find it statistically 21 significant. 22 Q. You don't have an ex -- expertise in 23 infectious disease; do you? 24 A. No. 25 Q. You're not a medical doctor.</p>	<p style="text-align: right;">Page 297</p> <p>1 (Exhibit 27 was marked for 2 identification.) 3 BY MR. SACCHET: 4 Q. Did you ask 3M to investigate the issue? 5 A. Of why they changed back? 6 Q. Yes. 7 A. No. 8 Q. Okay. This is a section from Breslow and 9 Day; correct? 10 A. Is it? I don't -- I don't know. It 11 doesn't -- 12 Oh, okay. Seems to be. 13 Q. And here on page 105 Breslow and Day state, 14 about in the middle of the page, paragraph begins "A 15 third way..." Do you see that? 16 A. Uh-huh. 17 Q. And the third sentence says, "Stratification 18 by factors which are not genuine confounding variables 19 would therefore increase the variability of the 20 estimates without eliminating any bias..." Do you 21 agree with that statement? 22 A. Trying to see what they're talking about 23 here. 24 MR. GORDON: I'm sorry, where are you? 25 MR. SACCHET: I'm on page 105 and the</p>

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<p style="text-align: right;">Page 298</p> <p>1 paragraph starting "A third way...", in the third 2 par -- in the third sentence. 3 A. Okay. They're talking about overmatching. 4 Okay. 5 Q. Yes. Okay. And then they say, "It is 6 commonly seen when data are stratified by a variable 7 known to be associated with exposure but not in itself 8 independently related to disease;" correct? 9 A. Yes. 10 Q. So to the extent that you have a factor and 11 you control for that factor, even though it's related 12 to the -- even though it's related to the treatment 13 but not necessarily the outcome, that will result in 14 unnecessary bias; correct? 15 MR. GORDON: Object to the form of the 16 question. 17 A. I don't think the term they're using is 18 "bias," I think they're talking about variability. 19 Q. Okay. So -- 20 A. That's different. 21 Q. Okay. You would agree to the extent that my 22 question involves variance or variability as opposed 23 to bias. 24 A. Okay. 25 Q. Okay.</p>	<p style="text-align: right;">Page 300</p> <p>1 variance. 2 A. That's -- that's an indication of precision. 3 Q. Okay. 4 A. Yeah. 5 Q. If we look at -- 6 A. And so what they're saying here is that 7 you've -- you've got a variable, there's no point in 8 controlling it. To control for bias, it's not going 9 to do anything to that, -- 10 Q. Okay. 11 A. -- and so you're just throwing it in there 12 unnecessarily and that's going to increase the 13 variance. 14 Q. Okay. 15 A. And so -- so I would -- I would agree with 16 that, but I would disagree that that corresponds to 17 that particular analysis on page six -- 18 Q. In -- 19 A. -- of my report. 20 Q. -- the bottom paragraph, the last full 21 sentence states, "Good evidence may be available from 22 previous studies that C is not causally related to 23 disease, in which case it should not be incorporated 24 as a confounder." Do you see that? 25 A. Yes.</p>
<p style="text-align: right;">Page 299</p> <p>1 A. So we're talking about vari -- variance and 2 not bias. Okay. 3 Q. Okay. So in the event that, for the sake of 4 argument, the thrombophylaxis is not in fact 5 related to the outcome of interest, which is deep 6 joint infection, if one were to control for the 7 thrombophylaxis, that would inject variance; 8 correct? 9 MR. GORDON: Object to the form of the 10 question, assumes facts not in evidence, incomplete 11 hypothetical. 12 A. I mean I think what you see -- what -- 13 What this is saying, if it's not, then they 14 would -- it would have no effect on the estimate but 15 it would increase the variance. 16 Q. Okay. 17 A. Okay? 18 Q. Yeah. 19 A. In the control that -- that I did in this 20 analysis, the estimate did change. 21 Q. And the confidence interval did, too; 22 correct? 23 A. And confidence -- 24 They both changed, yes. 25 Q. And that confidence interval measures</p>	<p style="text-align: right;">Page 301</p> <p>1 Q. Are you aware that the record studies found 2 that Xarelto is not related to infection? 3 MR. GORDON: Objection, asked and answered, 4 lack of foundation. 5 A. I think I said I had not looked at the 6 record studies. 7 Q. Would it be helpful to look at one? 8 A. I mean I -- it -- 9 When I was looking within the Albright 10 10 data set, I found the association that I reported. 11 Now I think the premise of your question is: Is the 12 association that I found, is that a causal association 13 or not? The way this study was designed, is this 14 temporal? You know, these time periods are changing. 15 And as I show in Fig. 2 -- 16 Q. Okay. 17 A. -- show in Fig. 2 and I present the -- 18 related to that I show in figure -- I'm sorry, on 19 page -- ah, where is that? On page four, the last 20 paragraph, it compares the infection rates by 21 quarter -- 22 Q. Yeah. 23 A. -- and we got a chi-square of 15.5 on six 24 degrees of freedom, p-value of .0167. So what that 25 suggests is that the incidence rates during the Bair</p>

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<p style="text-align: right;">Page 302</p> <p>1 Hugger period were changing quite a lot, and those 2 differences were statistically significant. 3 Q. Okay. 4 A. So this is not a period where things were 5 just under well controlled. 6 Q. Are you aware of whether deep joint 7 infections are always constant or whether there is 8 variability in deep joint infections more generally? 9 A. Well if there is variability more generally, 10 then that needs to be taken into account in the 11 analysis, and this analysis does not do that. 12 Q. When you conducted -- 13 A. I did not do that, and McGovern certainly 14 didn't do it either. 15 Q. When you construct a statistical model, the 16 confidence interval accounts for the variance of the 17 data; correct? 18 A. Well it should. But the confidence 19 intervals that I computed and the confidence intervals 20 that McGovern computed don't take that -- that 21 variability into account. 22 Q. Okay. 23 A. The expected value of this chi-square 24 statistic is equal to the degrees of freedom, so you 25 expect it to be six, in fact it's 15.5, so there's,</p>	<p style="text-align: right;">Page 304</p> <p>1 thinking there were other things going on is the 2 Gillson paper, for example, enumerates such a huge 3 array of things that were taking place at -- what is 4 it -- Northumbria group of hospitals, -- 5 Q. Okay. 6 A. -- so they were having a problem. 7 Obviously, NHS was -- was calling them on having a 8 high infection rate that they needed to do something 9 about, and the -- the Gissell paper elaborates on all 10 the things that they were trying to do to bring this 11 thing under control, and there were a lot of other 12 things other than switching to Hot Dog. 13 Q. Okay. Did you ask 3M for any info with 14 respect to this issue? 15 A. No. 16 MR. GORDON: Object to the form of the 17 question. 18 Q. Okay. Are you aware that in the Gillson 19 article the descriptor for infection is SSI? 20 MR. GORDON: Object to the form of the 21 question. 22 Q. The title of the article is SSI. 23 A. Which paper are you talking about? 24 Q. You just referenced the Gillson article, -- 25 A. Gillson, okay.</p>
<p style="text-align: right;">Page 303</p> <p>1 what, two and a half times as much variability as what 2 I would expect to see if the only variation that was 3 taking place was just a random fluctuation based on, 4 you know, what's going on with the use of -- of -- of 5 these surgical procedures at Wansbeck. 6 Q. You didn't do that calculation with respect 7 to the reanalysis of the Jensen data; correct? 8 A. I -- I didn't -- I didn't allow for random 9 variability other than the binomial variability -- 10 Q. Okay. 11 A. -- that -- that we assumed. No, I -- I took 12 that at a face value. And -- and it could be random. 13 My assumption is it's not random. My assumption is 14 it's due to other factors that are -- that were 15 affecting risk at Wansbeck during this time period. 16 Q. That's an assumption. 17 A. It is. 18 Q. Okay. I want to go back to the -- what we 19 were talking about with respect -- 20 Did you do any investigation to determine 21 whether your assumption was correct or not? 22 A. I -- I have no further -- 23 I have not been in contact with Wansbeck or 24 anyone else involved with this to know that for 25 certain. I guess a part of my -- my -- my reasons for</p>	<p style="text-align: right;">Page 305</p> <p>1 Q. -- "Implementing Effective SSI Measures." 2 A. Right. Yes. 3 Q. Do you know what "SSI" stands for? 4 A. Ahh, oh -- 5 I've forgotten. 6 Q. Surgical-site infection ring a bell? 7 A. Surgical-site infection. Exactly, yeah. 8 Q. Surgical-site infections are not the same 9 thing as deep joint infections. 10 MR. GORDON: Object to the form of the 11 question, lack of foundation, misconstrues the 12 evidence and assumes facts not in evidence. 13 Q. Do you know whether an SSI is the same as a 14 DJI? 15 MR. GORDON: Same objection. 16 A. It's -- it's not the same, it's not the same 17 thing. They are -- they would be -- 18 Are you saying -- suggesting they are not 19 related? 20 Q. I'm suggesting that -- 21 Do you know whether the measures that were 22 implemented in the Northumbria trust were specific to 23 SSI or DJI? 24 A. I think -- 25 Well the paper is entitled for SSI.</p>

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<p style="text-align: right;">Page 306</p> <p>1 Q. So you don't know whether they were specific</p> <p>2 to deep joint infection.</p> <p>3 A. Well I would assume that they would -- they</p> <p>4 would be effective on affecting both. I mean</p> <p>5 orthopedic surgery appears to be one of the things</p> <p>6 that they are in fact looking at.</p> <p>7 Q. Can you define SSI?</p> <p>8 A. I don't know the --</p> <p>9 I don't know. I'm -- it's not a -- an area</p> <p>10 that I've particularly done -- done work -- work on.</p> <p>11 I --</p> <p>12 Q. Can you define DJI?</p> <p>13 A. It's -- it's again the --</p> <p>14 It's joint -- joint infections --</p> <p>15 Q. Okay.</p> <p>16 A. -- that -- that you're looking at.</p> <p>17 Q. But you have no scientific basis or</p> <p>18 expertise to conclude whether or not the inter --</p> <p>19 interventions that are mentioned in the Gillson</p> <p>20 article which relate to SSI would have an impact on</p> <p>21 deep joint infection; correct?</p> <p>22 A. It's --</p> <p>23 They're not areas that I have -- that I</p> <p>24 have -- that I have personally done research on.</p> <p>25 My -- my --</p>	<p style="text-align: right;">Page 308</p> <p>1 A. I mean you -- you seem to be suggesting that</p> <p>2 there's no effect. Why -- why what you're asking</p> <p>3 me --</p> <p>4 Q. I would let --</p> <p>5 Your -- your report concludes that the SSI</p> <p>6 bundle may have had an effect on deep joint infection</p> <p>7 rates; correct?</p> <p>8 A. Yes. The things that they were doing to</p> <p>9 control SSI may have had an effect.</p> <p>10 Q. You have no scientific basis to make that</p> <p>11 conclusion.</p> <p>12 A. I'm -- no, no. I'm just -- just assuming</p> <p>13 that it does.</p> <p>14 Q. Thank you.</p> <p>15 Do you know if any articles that you're</p> <p>16 relying on relate to SSI versus DJI?</p> <p>17 A. No.</p> <p>18 Q. So you're not sure whether the publications</p> <p>19 that you've cited on page 14 of your report are</p> <p>20 specific to deep joint infection or a surgical-site</p> <p>21 infection.</p> <p>22 A. Oh. Some of them --</p> <p>23 I'm not sure which articles you're -- you're</p> <p>24 talking about.</p> <p>25 Q. Well do you know offhand? I don't want to</p>
<p style="text-align: right;">Page 307</p> <p>1 But I -- I believe that they would be</p> <p>2 related to each other. And things that you're doing</p> <p>3 to control SSI, my understanding is you would have --</p> <p>4 you would have effects on -- on PJI as well.</p> <p>5 Q. What's your understanding based on?</p> <p>6 A. Well looking at -- well I mean the -- one --</p> <p>7 This is from the -- from the Gillson paper.</p> <p>8 Q. What is?</p> <p>9 A. A patient with a -- with a -- with surgery</p> <p>10 on his knee.</p> <p>11 Q. Do you see the implant?</p> <p>12 A. I see the surgery on his knee.</p> <p>13 Q. Do you know whether that would result in</p> <p>14 either a superficial wound infection on the skin or</p> <p>15 whether it would result in a deep infection on a</p> <p>16 prosthetic?</p> <p>17 A. I don't know. If it was a deep infection, I</p> <p>18 think that would be something they would -- they would</p> <p>19 be interested in.</p> <p>20 You don't think that -- you don't think they</p> <p>21 would be interested in that as -- as respect to the</p> <p>22 surgery?</p> <p>23 Q. Are you asking me?</p> <p>24 A. Yeah.</p> <p>25 Q. I'm --</p>	<p style="text-align: right;">Page 309</p> <p>1 spend a ton of time on this.</p> <p>2 A. I don't -- I don't know offhand.</p> <p>3 Q. Okay.</p> <p>4 A. I --</p> <p>5 Q. With respect to the conclusions that you've</p> <p>6 offered in your report, did you distinguish between</p> <p>7 SSI and DJI?</p> <p>8 A. I don't know that you're --</p> <p>9 Most of what I was talking about in the</p> <p>10 report has to do with analysis of -- of -- of</p> <p>11 McGovern.</p> <p>12 Q. Do you know whether Albrecht 10, for</p> <p>13 example, contained data on SSI versus DJI?</p> <p>14 A. I don't recall that it -- it did. I think</p> <p>15 it was basically looking at the -- the internal</p> <p>16 infections.</p> <p>17 Q. But you don't know whether those infections</p> <p>18 were SSI or DJI.</p> <p>19 A. I --</p> <p>20 MR. GORDON: Object to the form of the</p> <p>21 question.</p> <p>22 A. I wasn't --</p> <p>23 They were looking at in -- in -- whatever</p> <p>24 their definition was of -- of infection.</p> <p>25 Q. But you don't know what that is.</p>

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<p style="text-align: right;">Page 310</p> <p>1 A. They de --</p> <p>2 I don't re -- recall exactly what the detail</p> <p>3 is there. They defined it in -- it's defined in</p> <p>4 McGovern, and it's identified as one of the variables</p> <p>5 that is in Albrecht -- Albrecht 10.</p> <p>6 Q. Albrecht 10 says what they're defined as,</p> <p>7 whether they are DJI or SSI?</p> <p>8 A. I don't recall if it said that. It just</p> <p>9 said a --</p> <p>10 Q. I'll represent to you that it doesn't.</p> <p>11 A. Okay.</p> <p>12 Q. So you're not sure one way or the other</p> <p>13 whether the data in Albrecht Exhibit 10 is specific to</p> <p>14 SSI versus DJI, considering that the Gillson article</p> <p>15 is talking about SSI.</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, assumes facts not in evidence.</p> <p>18 A. I was using the definition that -- that was</p> <p>19 in Albrecht 10.</p> <p>20 Q. Where is the definition in Albrecht 10?</p> <p>21 A. Well they defined it to -- to define their</p> <p>22 variable that indicated --</p> <p>23 What was the variable called?</p> <p>24 Q. It's not in there; is it, professor?</p> <p>25 A. Well there's one of the -- it's one of these</p>	<p style="text-align: right;">Page 312</p> <p>1 Q. And there was a change from Gentamicin to</p> <p>2 Gentamicin plus Teicoplanin; correct?</p> <p>3 A. That's correct.</p> <p>4 Q. And the change happened at the tail end of</p> <p>5 the Bair Hugger period with some time left, and then</p> <p>6 it was fully in force during the Hot Dog period;</p> <p>7 correct?</p> <p>8 A. Yeah.</p> <p>9 MR. GORDON: Well I'll object to the form of</p> <p>10 the question.</p> <p>11 Q. Are you aware of the relationship between</p> <p>12 using prophylactic antibiotics on DJI versus SSI?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question, lack of foundation.</p> <p>15 A. I'm not familiar with that, no.</p> <p>16 Q. Did you conduct any research to determine</p> <p>17 how antibiotics operate as to the outcome of DJI</p> <p>18 versus SSI?</p> <p>19 A. No.</p> <p>20 Q. Did you ask 3M for any information about how</p> <p>21 change from Gentamicin to Gentamicin plus Teicoplanin</p> <p>22 might affect deep joint infection rates?</p> <p>23 A. No.</p> <p>24 Q. Do you have any knowledge of how Gentamicin</p> <p>25 versus Gentamicin and Teicoplanin affects joint</p>
<p style="text-align: right;">Page 311</p> <p>1 columns. They are -- they are labeled, and somewhere</p> <p>2 in here --</p> <p>3 I've forgotten the variable names that they</p> <p>4 used.</p> <p>5 Q. Do you see it?</p> <p>6 A. Deep infection.</p> <p>7 Q. Do you know whether that's DJI or SSI?</p> <p>8 A. I don't know.</p> <p>9 Q. Okay. Do you know whether --</p> <p>10 A. Well DJ -- I think it's DJ -- DJI, that DJI</p> <p>11 is deep joint infection.</p> <p>12 Q. Do you know whether the mechanism of</p> <p>13 infection differs between the DJI and SSI?</p> <p>14 A. No.</p> <p>15 Q. Okay. I'd like to turn back to the Breslow</p> <p>16 and Day article that we were looking at, which has</p> <p>17 been marked as Exhibit 26 I believe.</p> <p>18 THE REPORTER: Before we do that, let's go</p> <p>19 off the record, take five minutes.</p> <p>20 (Recess taken.)</p> <p>21 BY MR. SACCHET:</p> <p>22 Q. Professor Holford, you have also analyzed</p> <p>23 the change in the antibiotic regime that occurred</p> <p>24 during the McGovern study; correct?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 313</p> <p>1 infection rates?</p> <p>2 A. Other than the -- the analysis that I did</p> <p>3 using Albrecht 10, that -- that's basically what I was</p> <p>4 using.</p> <p>5 Q. In your report you assume that the</p> <p>6 thromboprophylaxis may be a confounding factor, but</p> <p>7 you never state as much with respect to the</p> <p>8 antibiotic; is that true?</p> <p>9 A. I don't know if I stated it. It is -- it is</p> <p>10 potentially a -- a -- a confounding variable and in</p> <p>11 fact I did adjust for it in -- I did present an</p> <p>12 analysis where I adjusted for it.</p> <p>13 Q. So did you adjust for the antibiotic without</p> <p>14 considering whether it was a confounding factor?</p> <p>15 A. Well, I mean whether it's a confounding</p> <p>16 factor, as I -- as I said before, it -- it depends on</p> <p>17 whether -- whether there is a change in the --</p> <p>18 It affects the -- the association.</p> <p>19 Q. Okay.</p> <p>20 A. And in this case the association -- let's</p> <p>21 see.</p> <p>22 When we just controlled for the</p> <p>23 thromboprophylaxis --</p> <p>24 Q. I think we're on the antibiotic.</p> <p>25 A. Yes. When we just controlled for -- for</p>

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<p style="text-align: right;">Page 314</p> <p>1 the -- for the thromboprophylaxis, the -- the odds 2 ratio was, what, 2.49? Is that right? No, I'm sorry, 3 2.16. 4 Q. That's the odds ratio for controlling for 5 the thromboprophylaxis; correct? 6 A. From -- from -- 7 Yes, right. 8 Q. And we're talking about the antibiotic. 9 A. And then so now when we add, in addition to 10 controlling for the thromboprophylaxis we're adding 11 the antibiotic, which is what you were asking about -- 12 Q. Well I actually wasn't asking about that. 13 I'm asking for just with respect to the antibiotic, 14 not controlling for both, just controlling for the 15 antibiotic. You did that calculation prior to the 16 double control; correct? 17 A. I don't know that I did the single control. 18 Q. Okay. 19 A. I looked -- I looked -- 20 I did a double control. 21 Q. You don't recall doing a single control on 22 the antibiotic? 23 A. I don't think I did. 24 Q. Well you did. 25 A. Oh, I did? Okay.</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. Yeah. 2 A. Sure. 3 Q. And protocol one, which we'll call the 4 Gentamicin administration, resulted in an infection 5 rate of 1.92 percent in patients; correct? 6 A. Yes. 7 Q. Okay. And then protocol two, when 8 Gentamicin plus Teicoplanin was used, the rate went up 9 to 3.13; correct? 10 A. That's right. 11 Q. That's an increase in the infection rate; 12 correct? 13 A. Yes. 14 Q. And that's the combination of antibiotics 15 that was used during the Hot Dog period; correct? 16 A. Yes. 17 Q. So actually, the combination of antibiotics 18 that was used resulted in a higher infection rate 19 between -- compared to the drug that was used with 20 just Bair Hugger patients; correct? 21 A. That's right. 22 Q. So if anything -- 23 A. Yeah. It's the com -- wait. 24 That's right. Yeah. 25 Q. Okay.</p>
<p style="text-align: right;">Page 315</p> <p>1 MR. GORDON: On page six. 2 Q. It's on page six. 3 A. Oh, I'm sorry. 4 Q. Right under the heading "Comparison of the 5 effect of antibiotic regimen on study results." And 6 you report that there was a rate of infection during 7 the Bair Hugger period when Gentamicin was used of 8 1.92 percent; correct? 9 A. Oh, okay. This is -- 10 Yeah. We were -- I think we were talking 11 about two different things. This is, I think, just 12 looking at the effect of an antibiotic on -- 13 Q. Yes. 14 A. Yeah. 15 Q. Okay. 16 A. I was talking about controlling for it. 17 Yeah. 18 Q. Okay. So here we essentially controlled for 19 the use of the Bair Hugger and viewed infection rates 20 when Gentamicin was applied versus when Gentamicin 21 plus Teicoplanin was applied; correct? 22 A. That's right. Because it's only during 23 the -- 24 Q. Yeah. 25 A. -- Bair Hugger.</p>	<p style="text-align: right;">Page 317</p> <p>1 A. The switchover. Okay. Sorry. 2 Q. So if anything, there's actually reverse 3 confounding in the direction that the use of 4 Gentamicin plus Teicoplanin was less effective than 5 the use of just Gentamicin; correct? 6 A. It appears to be, yes. 7 Q. So based on that conclusion, the odds ratio 8 as reported in the McGovern study could even be higher 9 in the event that we controlled for the use of 10 Gentamicin plus Teicoplanin; correct? 11 A. Well -- 12 Q. You just told me statistical significance 13 did not matter. 14 MR. GORDON: Object to the form of the 15 question, misstates his testimony. 16 A. I mean the issue of it being a confounder is 17 does it affect the association -- does it affect the 18 measure of association between -- the -- 19 Well, in this case we're looking at Bair 20 Hugger, Bair Hugger/Hot Dog, does it -- does it affect 21 that association. 22 Q. You didn't report an association; did you? 23 MR. GORDON: Object to the form of the 24 question. 25 A. Yeah, it --</p>

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<p style="text-align: right;">Page 318</p> <p>1 Q. Did you report an association with respect 2 to controlling for the antibiotic in the Bair Hugger 3 arm of the study? 4 MR. GORDON: Just the antibiotic? 5 MR. SACCHET: Yeah. 6 A. Not just the antibiotic, no. That's what I 7 said, I didn't do that. 8 Q. You didn't do that. 9 A. Look at the effect of -- 10 Well I -- I looked at the effect of -- of 11 the antibiotic -- 12 Q. Yeah. 13 A. -- on risk of infection, -- 14 Q. Okay. 15 A. -- and that was this difference of, oh, 1.9 16 versus 3.1 infection rate with a p-value of .17. 17 Q. Okay. And the percent of infection when 18 using Gentamicin plus Teicoplanin went up compared to 19 the use of just Gentamicin; correct? 20 A. That's right. 21 Q. And in the McGovern study, all the Hot Dog 22 patients received Gentamicin plus Teicoplanin; 23 correct? 24 A. Yeah. 25 Q. This calculation that you performed shows</p>	<p style="text-align: right;">Page 320</p> <p>1 ratio with respect to that calculation; correct? 2 A. No, it does -- 3 No, I have not. 4 Q. So in order to determine whether there was 5 reverse confounding or general confounding, you have 6 not made the calculation in order to make that 7 conclusion; correct? 8 A. I haven't said whether or not it's reverse 9 or -- 10 I'm not -- I'm not sure what -- what you 11 mean by "reverse" or -- 12 Q. That's what I said, "whether or not." You 13 don't know whether there was confounding because you 14 haven't reported an odds risk ratio with respect to 15 just the control for the antibiotic; correct? 16 A. Well it's not just control. I've -- I've 17 controlled for both antibiotic and thrombo. 18 Q. I understand. But with respect to 19 controlling for the antibiotic in this calculation -- 20 A. Yes. 21 Q. -- you report infection rates and you report 22 a p-value, you do not report an odds ratio; correct? 23 A. That's correct. 24 Q. There is no way to determine whether the 25 odds ratio increased compared to what was provided in</p>
<p style="text-align: right;">Page 319</p> <p>1 that Gentamicin may be less effective than Gentamicin 2 plus Teicoplanin; correct? 3 A. It -- it -- 4 The point estimates go in that direction. 5 It's not -- 6 Q. Okay. 7 A. -- statistically significant, -- 8 Q. Okay. 9 A. -- although it's -- 10 It's sort of unclear as to whether or not it 11 does. 12 Q. With respect to confounding, you previously 13 stated that statistical significance is not 14 determinant of whether there is confounding; correct? 15 A. That's right. 16 Q. So whether or not the p-value is .1683 does 17 not mean that there was reverse confounding with 18 respect to the odds ratio reported in the McGovern 19 study; correct? 20 A. It's -- it -- 21 Well it basically means that it's -- it's -- 22 it's -- it could go either way. 23 Q. It could -- 24 A. It's not -- it's not clear. 25 Q. Okay. And you have not reported an odds</p>	<p style="text-align: right;">Page 321</p> <p>1 the McGovern study or whether it decreased, 2 correct, -- 3 A. Which odds -- 4 Q. -- when com -- 5 A. -- ratio are you talking about? 6 Q. Either the 3.8 or the 2.76 that you 7 calculated based on Albrecht 10. You have no basis to 8 compare those odds ratios to this calculation. 9 A. Well I compared the odds -- I mean I 10 didn't -- 11 I don't report the odds ratio, but you can 12 pretty good -- get a pretty good idea of what -- about 13 what it's going to be -- 14 Q. You told me -- 15 A. -- because the infection rate -- let's see. 16 "In order to control for the...one must use 17 the Bair Hugger period that -- that shares the 18 antibiotic and thromboprophylaxis regimen used in the 19 Hot Dog period," so -- which had an infection rate of 20 three out of 270, 1.1 percent, and compare that with 21 four out of 372, which is 1.08 percent. 22 Q. You're looking at controlling for both 23 variables, correct, right now? 24 A. That is correct. 25 Q. I want to go back to when you just</p>

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<p style="text-align: right;">Page 322</p> <p>1 controlled for the antibiotic, which is what we're 2 talking about. You did not provide an odds ratio. 3 A. I did not -- 4 That's right, I didn't provide it. 5 Q. You did not determine how or whether the 6 antibiotic by itself is a confounding variable. 7 A. By -- by itself, no. By itself, no. 8 Q. And you have -- 9 A. But I've controlled for both of them -- 10 Q. We'll get there. I'm just talking about 11 this calculation. 12 You do not know the degree of confounding, 13 if any, caused by only the antibiotic. 14 A. That's right. I didn't do that. 15 Q. And you have not reviewed any literature to 16 suggest that an antibiotic is a confounding factor on 17 deep joint infections. 18 MR. GORDON: Object to the form of the 19 question. 20 A. I don't see -- understand that -- understand 21 your -- your question. To be a confounding variable, 22 as we've said, it has to be associated with -- with 23 the -- with the outcome -- 24 Q. Okay. 25 A. -- and the variable you're looking at.</p>	<p style="text-align: right;">Page 324</p> <p>1 A. The one -- the one is higher. It's not -- 2 That difference is not statistically 3 significant. 4 Q. Okay. Based on that -- 5 A. When I -- when I added that into the 6 analysis and controlled for that after I had already 7 controlled from thromboprophylaxis, the -- any 8 association that -- an association that was 2.1 -- 9 six was it? -- com -- disappeared effectively 10 completely, I mean 1 -- 1. -- 1.11 percent versus 11 1.08. 12 Q. Okay. Let's talk about -- 13 A. So they're basically -- I mean it -- as -- 14 It would, I -- I -- I suggest, be an 15 indication that this is a confounding variable because 16 the odds ratio is bas -- basically eliminated. 17 Q. Have you done a powering analysis of this 18 double-control calculation? 19 A. A power analysis, no. 20 Q. You have no idea whether this is adequately 21 powered. 22 A. Oh, it's -- I -- there's -- 23 There's never been a power analysis of 24 anything related to McGovern. 25 Q. You don't know whether this calculation --</p>
<p style="text-align: right;">Page 323</p> <p>1 Q. Yeah. And you haven't done -- 2 A. So whether or not it's associated with -- 3 Well in this study it -- it certainly is 4 associated with -- with whether or not the Bair Hugger 5 or the Hot Dog was used. In general, who knows? 6 Q. You don't know whether -- 7 A. Well -- 8 Q. -- the Gentamic -- 9 A. -- it depends on what -- what -- what is 10 done by the institution. 11 Q. You don't know whether Gentamicin is more or 12 less effective than Gentamicin plus Teicoplanin -- 13 A. Well that's a different question. 14 Q. -- in terms of deep joint infection. That's 15 the question right now. Do you know? 16 A. Well there is the -- 17 The analysis based on these data -- 18 Q. That shows -- 19 A. -- found -- found the -- the result was not 20 statistically significant, the difference of 2.19 21 percent versus 3.1, but -- but -- 22 Q. And the infection rate went up with 23 Gentamicin plus Teicoplanin. 24 A. That's right. 25 Q. Okay.</p>	<p style="text-align: right;">Page 325</p> <p>1 A. I don't -- I mean why are -- 2 What is the issue? The power to do what? I 3 don't know what you're asking. 4 Q. You're analyzing a population of 270 persons 5 and 372 persons, totaling approximately 600 people; 6 correct? 7 A. So what's your -- what's your hypothesis? 8 Q. My question is: If the McGovern study was, 9 in your words, a relatively small population based on 10 the incidence of infection and was therefore 11 unreliable, -- 12 A. Yeah. 13 Q. -- you've cut the population in half. 14 A. Okay. 15 Q. Doubly unreliable. 16 A. Well whether it's double or not, I -- it's 17 not -- it's un -- it's unclear. 18 Q. More unreliable. 19 A. It -- it will be more -- more -- it will 20 have less -- 21 The study would have -- would have even less 22 power, that's true. 23 Q. More unreliable. 24 A. What do you mean by "reliable?" 25 Q. More variance.</p>

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<p style="text-align: right;">Page 326</p> <p>1 A. More variance, yes.</p> <p>2 Q. If anything, the best way to figure out</p> <p>3 whether the thromboprophylaxis and the antibiotic</p> <p>4 confounded the results in a population of patients who</p> <p>5 were subjected to Bair Hugger warming versus Hot Dog</p> <p>6 warming would be to look at a larger sample size when</p> <p>7 both of those variables are controlled; correct?</p> <p>8 A. Well one would have to look at what the --</p> <p>9 What I think is needed is a proper</p> <p>10 protocol --</p> <p>11 Q. Okay.</p> <p>12 A. -- which would address the issue of power,</p> <p>13 and you would have to specify what magnitude of effect</p> <p>14 you wanted -- wanted to detect, --</p> <p>15 Q. Okay.</p> <p>16 A. -- and this, as far as I can tell, was never</p> <p>17 done by this group.</p> <p>18 Q. Okay. I'm going to ask the question again</p> <p>19 because that didn't respond to it.</p> <p>20 A better analysis than what you have done</p> <p>21 here with respect to controlling for both var --</p> <p>22 variables would be to look at a larger population of</p> <p>23 patients who received the same thromboprophylaxis and</p> <p>24 the same antibiotic; correct?</p> <p>25 A. Well --</p>	<p style="text-align: right;">Page 328</p> <p>1 McGovern.</p> <p>2 Q. Okay. But my question is different. The</p> <p>3 recent Augustine article has a larger patient</p> <p>4 population; --</p> <p>5 A. It's a larger patient population.</p> <p>6 Q. -- correct?</p> <p>7 A. It is a larger patient population. I think</p> <p>8 it is, yes.</p> <p>9 Q. And the article notes that there was no</p> <p>10 change in the thromboprophylaxis or the antibiotic</p> <p>11 regimen; correct?</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question, assumes facts -- mis -- it completely</p> <p>14 misstates the evidence.</p> <p>15 A. I -- the -- the --</p> <p>16 The paper says very little about -- very --</p> <p>17 very little detailed about -- about -- about the</p> <p>18 population. I think it says that, yes.</p> <p>19 Q. Okay. So we've established that it's a</p> <p>20 larger population and that the study does say that</p> <p>21 there was not a change in the thromboprophylaxis or</p> <p>22 antibiotic; is that correct?</p> <p>23 MR. GORDON: Counsel, it doesn't -- it</p> <p>24 doesn't say that. Let him read it if you're going to,</p> <p>25 you know, make it up, make up stuff.</p>
<p style="text-align: right;">Page 327</p> <p>1 Q. There would be less variance.</p> <p>2 A. Oh, if you -- if you -- if you restricted</p> <p>3 both of those, but I mean that's not your only option.</p> <p>4 If you restricted it to those groups and had an</p> <p>5 increased sample size, that would -- that would</p> <p>6 certainly give you more power.</p> <p>7 Q. Yeah. It would -- it would be a more</p> <p>8 accurate representation of whether those two variables</p> <p>9 were confounders or not; correct?</p> <p>10 A. If that's what you were interested in.</p> <p>11 Q. Okay. It would be a more accurate</p> <p>12 representation as to whether there in fact is an</p> <p>13 increased odds ratio; correct?</p> <p>14 A. For -- for --</p> <p>15 Q. The use of the device and the outcome of</p> <p>16 infection.</p> <p>17 A. The use of the device. It would give a</p> <p>18 better estimate of that, yes.</p> <p>19 Q. Okay. The recent Augustine study does that;</p> <p>20 correct?</p> <p>21 A. The -- this is the published -- the one that</p> <p>22 was just published?</p> <p>23 Q. Yeah.</p> <p>24 A. Well, I mean the recent study has its own --</p> <p>25 has a -- has the potential for bias that is also in</p>	<p style="text-align: right;">Page 329</p> <p>1 THE WITNESS: Where specifically does it say</p> <p>2 that?</p> <p>3 MR. SACCHET: Okay.</p> <p>4 THE WITNESS: Have you got it?</p> <p>5 (Exhibit 28 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. SACCHET:</p> <p>8 Q. Is this a copy of the recent Augustine</p> <p>9 publication in Orthopedic Reviews?</p> <p>10 A. Yes, it is.</p> <p>11 Q. Okay. We can see that on page one there is</p> <p>12 a subject header entitled "Materials and Methods;"</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. In the bottom right-hand corner.</p> <p>16 And it says, "This study is designed to</p> <p>17 investigate periprosthetic joint infection (PJI) rates</p> <p>18 while using FAW (Bair Hugger, 3M, St. Paul, Minnesota,</p> <p>19 USA) compared with air-free CFW (HotDog, Augustine</p> <p>20 Temperature Management, Eden Prairie, USA);" correct?</p> <p>21 A. Yes.</p> <p>22 Q. The next paragraph says, "Each hospital</p> <p>23 report shares a study design similar to the McGovern</p> <p>24 study;" correct?</p> <p>25 A. Yes.</p>

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<p style="text-align: right;">Page 330</p> <p>1 Q. "In each study, a baseline PJI rate was 2 determined for the FAW control group over a one-year 3 period of time. FAW was then discontinued, and the 4 hospital switched to air-free CFW warming;" correct? 5 A. Yes. 6 Q. Okay. The top of the next column says, 7 "Only hospitals reporting that no other significant 8 changes were made to their surgical and antibiotic 9 prophylaxis protocols during the study period 10 qualified to be part of this study." Do you see that? 11 A. Yes. 12 Q. It says that there were no changes to 13 antibiotic prophylaxis protocols; correct? 14 A. That's what it says, yes. 15 Q. Do you have any reason to doubt that? 16 A. I -- I don't know. I mean that's what -- 17 that's what it says. I don't -- it -- it -- 18 I mean we have very little detail here 19 about -- about any variables other than the -- other 20 than the device that was used -- 21 Q. Okay. Do you have any -- 22 A. -- on the patients or -- 23 I mean there's no table here giving basic 24 demographics about the -- about the patient 25 population.</p>	<p style="text-align: right;">Page 332</p> <p>1 A. -- is pretty remarkable. 2 Q. What is here? There's a statement that says 3 "Only hospitals reporting that no other significant 4 changes were made to their surgical and antibiotic 5 prophylaxis protocols during the study period 6 qualified to be part of this study." 7 A. Okay. 8 Q. Do you have any basis, scientific or 9 otherwise, to doubt the veracity of that statement? 10 A. No. 11 Q. If we look at Table 1, there are three 12 centers denominated in the table; correct? 13 A. That's correct. 14 Q. And the first center has broken down between 15 conductive fabric and forced air; correct? 16 A. Yes. 17 Q. And the odds ratio, based on the increase in 18 infection from the use of forced air instead of 19 conductive fabric, is 4.59 as reported in this study; 20 correct? 21 A. That's what they report, yeah. 22 Q. Okay. That's the question. 23 The second center also evaluates the change 24 from conductive fabric to forced air and it finds an 25 odds ratio of 11.47 as reported in Table 1; correct?</p>
<p style="text-align: right;">Page 331</p> <p>1 Q. Demographics are different than whether 2 there were changes to the surgical and antibiotic 3 prophylaxis protocols; correct? 4 A. They are diff -- they are, but I mean all -- 5 all I'm -- all I'm indicating is that details -- 6 Q. Okay. 7 A. -- related to what was done in this study 8 are pretty skimpy. 9 Q. Have you tried to investigate the details 10 that you would otherwise like to know? 11 A. Oh. I mean you can look at any other paper. 12 I mean there's lots of reports on the -- on the -- on 13 the characteristics of the patients, what's the age 14 distribution of the patients that they're looking 15 at, -- 16 Q. Have you contact -- 17 A. -- how many males, how many females there 18 were, -- 19 Q. Okay. 20 A. -- what is the racial distribution of the -- 21 Q. Okay. 22 A. -- of the -- of the paper. I mean there's 23 a -- the -- 24 The list of things that are not here -- 25 Q. Okay.</p>	<p style="text-align: right;">Page 333</p> <p>1 A. That's what they report. 2 Q. Both of those odds ratios are higher than 3 what was reported in the McGovern study; correct? 4 A. That's true. 5 Q. The second odds ratio of 11.47 is almost 6 three times the size of what was reported in the 7 McGovern study; correct? 8 A. That's the -- the -- 9 You're -- you're referring to just the point 10 estimate. 11 Q. Just the odds ratio. 12 A. Just the point estimate. 13 Q. Yeah, that's the question. 14 A. It is large. It is large, yes. 15 Q. Okay. And the center three, in all 16 fairness, reported a 1.33 odds ratio; correct? 17 A. That's right. 18 Q. The multi-center pooled results based on 19 those three institutions totaling a population of over 20 2,000 persons -- 21 Correct? 22 A. Yes. 23 Q. -- found a collective odds ratio of 4.28; 24 correct? 25 A. That's right.</p>

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<p style="text-align: right;">Page 334</p> <p>1 Q. That is higher than what's reported in the 2 McGovern study; correct? 3 A. That point estimate is higher. 4 Q. It's doubled in the size of the odds ratio 5 of 2.16 that you reported in your study. 6 A. It's twice -- twice that, yes. 7 Q. It's four times the size of the odds ratio 8 that you reported when controlling for both the 9 thromboprophylaxis and the antibiotic; correct? 10 A. That's correct. 11 Q. The population is four times the size. 12 A. That's -- 13 Is it four times? 14 Q. Your population was approximately 600 15 persons. 16 A. Oh, oh, I see that's how you use that. 17 Yeah, that's true. Yes. 18 Q. Okay. Based on this size of the 19 population -- well strike that. 20 The p-value for the multi-center pooled 21 result is .002; correct? 22 A. That's right. 23 Q. That is a statistically significant p-value; 24 correct? 25 A. That is. The -- the -- the confidence</p>	<p style="text-align: right;">Page 336</p> <p>1 A. Yes. 2 Q. Okay. 3 MR. GORDON: Are you talking about 4 "Causation findings," that section? 5 THE WITNESS: Yeah, I think that's what he's 6 citing. 7 MR. SACCHET: Yeah. That was inartful. 8 Q. The first factor that you analyzed was the 9 temporality -- 10 A. Yeah. 11 Q. -- of -- of this -- of this data. 12 You agree that temporality is met with 13 respect to the Bair Hugger and the risk of increased 14 infection, however; correct? 15 A. Yes, I do. 16 Q. Okay. You also assume that it's possible 17 that temporality may be met with respect to the 18 thromboprophylaxis; correct? 19 A. Yes. 20 Q. We discussed earlier that the McGovern study 21 states that the thromboprophylaxis is applied 22 postoperatively; correct? 23 A. Yes. 24 Q. You -- 25 Do you know the rate in which an infection</p>
<p style="text-align: right;">Page 335</p> <p>1 interval is still 10. 2 Q. It's half the size of the confidence 3 interval you reported in the Jensen reanalysis; 4 correct? 5 A. The -- 6 For that particular association, yes. But 7 it's not that different from the confidence interval 8 that was reported in McGovern. 9 Q. Okay. If we could -- 10 A. May I -- 11 There are other aspects of this -- of 12 this -- of this -- 13 Q. I haven't asked about them, so perhaps -- 14 A. I know you haven't asked about them, but 15 you -- 16 Q. -- perhaps you can explain them when Mr. 17 Gordon -- 18 A. Okay. 19 Q. -- asks you some questions. 20 With respect to the conclusions that you 21 offer in the epi section of your report -- 22 MR. GORDON: What section? 23 Q. -- the epidemiology section of your report 24 regarding drawing causal inferences, there is that 25 part of your report; right?</p>	<p style="text-align: right;">Page 337</p> <p>1 forms on a prosthetic upon a bacteria landing on the 2 prosthetic? 3 Let me rephrase. It was not a good 4 question. 5 Do you know how quickly an infection may 6 manifest after a bacteria lands on a prosthetic 7 implant? 8 A. No, I don't. I mean I -- the -- 9 Using the -- this part of the -- the 10 protocol, it is the same for -- for -- for McGovern's 11 study as it was for, you know, the Jensen study, 12 and -- and so they were -- they were using the same 13 method, so whatever the temporality is related to that 14 variable I assume is about the same. 15 Q. So my question, though, is: You don't know 16 whether or not a deep joint infection could occur 17 within an hour of a bacteria landing on the implant. 18 A. Could it have -- I'm not -- 19 I don't know how long it takes. It often -- 20 it -- it may take longer, and may take longer for the 21 diagnosis to come -- come in. 22 Q. It could be shorter than an hour. 23 MR. GORDON: Objection, lack of foundation. 24 A. I don't -- I don't know how long it takes. 25 Q. You don't know.</p>

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<p style="text-align: right;">Page 338</p> <p>1 A. It's not -- it's not reported. I think it's 2 reported how long after the surgery -- 3 Q. Up to 60 days; correct? 4 A. Up to 60 days. But some of that I assume is 5 lab time and all that stuff. 6 Q. Yeah. 7 A. And so who knows? 8 Q. Okay. 9 A. It's not addressing the question that you're 10 asking I don't think. 11 Q. Well -- yeah. So my question really is: To 12 the extent that a deep joint infection may occur 13 within a matter of hours after surgery, temporality is 14 not met in the event that the thromboprophylaxis is 15 applied a day after the surgery. 16 A. If it occurs within hours. Well I mean -- 17 Q. The bacteria causes an infection within a 18 matter of hours -- 19 A. Yeah, but it -- what -- 20 You're not observing it until 60 days later. 21 Q. That's possible. But of course -- 22 A. So if you're observing it at that point -- 23 I mean the infection could have started 24 within hours and then you apply the -- imply 25 the -- apply the -- the anti -- antibiotic and it</p>	<p style="text-align: right;">Page 340</p> <p>1 A. I didn't analyze the temporal -- the -- how 2 long it took for the -- for the -- how -- when -- when 3 the infection -- infection occurred. 4 Q. Uh-huh. 5 A. Those data I don't think were reported on -- 6 on the data that I was looking at. 7 Q. So you don't know whether temporal -- 8 A. So I don't know whether the in -- there was 9 an infection at that point in time. I -- the data -- 10 When I compared the dates of the diagnosis 11 to when the surgery was done, I don't recall there 12 being -- I mean I went over the inci -- incidences, I 13 don't recall instances where they were diagnosed on 14 the same day. 15 Q. Okay. But you're not sure whether 16 temporality is satisfied in all cases with respect to 17 the thromboprophylaxis because you don't know how 18 quickly an infection manifests; is that true? 19 A. I -- I didn't specifically look at that. I 20 suspected that it was, but it -- it -- it -- it -- 21 it -- it's possible that it wasn't. 22 Q. You don't know. 23 A. I -- I don't know. I don't -- I don't know. 24 Q. Okay. 25 A. But there again, I mean the temporality is</p>
<p style="text-align: right;">Page 339</p> <p>1 kills whatever happened to be there. 2 Q. You're talking about the thromboprophylaxis, 3 which is a blood thinner; correct? 4 A. Okay. The blood thinner, whatever effect 5 that is having. 6 Q. Yeah. 7 A. I don't know -- 8 Q. You don't know whether there is an effect. 9 A. Don't -- I -- 10 I don't know. There is an association -- 11 Q. Okay. 12 A. -- in -- in this particular study, -- 13 Q. Okay. 14 A. -- so that -- which -- which would suggest 15 if it's not a causal effect, it's at least -- it's -- 16 it's confounded by the same types of factors that 17 could be confounding the association that -- that -- 18 with the device that's being reported by McGovern. 19 Q. But in the event that an infection does in 20 fact occur within hours of a surgery, application of a 21 thromboprophylaxis a day later does not satisfy 22 temporality. 23 MR. GORDON: Objection, lack of foundation, 24 incomplete hypothetical, assumes facts not in 25 evidence.</p>	<p style="text-align: right;">Page 341</p> <p>1 important for finding the association for what 2 occurred during the time period that -- that the 3 particular form of prophylaxis was applied, because 4 that could be -- it -- it could be in fact due to 5 something else because of the way this study was done. 6 It was only done by looking at certain dates. So what 7 happened? And of course a lot of things could be 8 happening during these dates, because as -- as the -- 9 this -- this study is related to -- 10 All the changes that were taking place with 11 regard to SSI, which quite possibly were also 12 affecting the -- the -- the deep joint infections, 13 were taking place during this time period, and so 14 that -- it could be something in that that is being 15 indirectly controlled when I'm controlling for the 16 thromboprophylaxis. 17 Q. The bottom line is that there's no doubt 18 temporality is satisfied with respect to the Bair 19 Hugger and incidence of infection; however, there is 20 potential doubt with respect to any of the other 21 factors that you've noted in your report. 22 MR. GORDON: Object to the form of the 23 question, lack of foundation, assumes facts not in 24 evidence. 25 A. There is -- there's the potential --</p>

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<p style="text-align: right;">Page 342</p> <p>1 Q. Let me ask the question again. There's no 2 question that temporality is satisfied with respect to 3 the Bair Hugger. You've said as much in your report. 4 A. Yes. 5 Q. There is a question as to whether 6 temporality is satisfied with respect to the 7 thromboprophylaxis and any other of the -- of the 8 measures that were part of the SSI bundle. 9 MR. GORDON: Same objections. 10 Q. You don't know whether temporality is 11 satisfied as to those variables; do you? 12 A. With regard to -- 13 Q. The thromboprophylaxis. Do you know? 14 A. -- thromboprophylaxis -- 15 Q. Do you know? 16 A. I don't know exactly when it -- when it 17 was -- we -- 18 We don't have data on the timing -- 19 Q. Okay. 20 A. -- of it, but -- 21 Q. So you don't know. 22 A. So -- 23 Q. It's really "yes" or "no." 24 A. I -- 25 Well I don't have sufficient detail to</p>	<p style="text-align: right;">Page 344</p> <p>1 A. Well it's one of the factors that's looked 2 for, and in fact one of the factors that was addressed 3 that -- that Samet uses. 4 Q. The question is different and that is: 5 Temporality is a required factor to draw causal 6 inference; correct? 7 A. Yes. 8 Q. The strength of association -- 9 A. Is another factor that -- 10 Q. -- is another factor, but is not a 11 prerequisite for drawing causal inference. 12 A. Okay. 13 Q. Okay. The strength of association goes to 14 the magnitude of causation as opposed to the presence 15 of causation; correct? 16 MR. GORDON: Object to the form of the 17 question. 18 Q. You stated earlier -- 19 A. It's not looking at the mag -- but the -- 20 I don't know what you mean by the magnitude 21 of the causation. 22 Q. The odds -- 23 A. It's either causing or it's not causing. 24 Q. The odds ratio -- 25 A. The association has a magnitude, so I'm not</p>
<p style="text-align: right;">Page 343</p> <p>1 really -- to really be able to -- to -- to nail it 2 down -- 3 Q. Okay. 4 A. -- as to when it is. I -- 5 Q. Thank you. 6 A. I suspect it probably is, but it's unclear. 7 And I think I say -- well it -- it's -- 8 I think it's potentially controlled for, 9 yes. 10 Q. Okay. 11 A. It's not -- 12 Q. It's unclear. 13 A. Yes. 14 Q. The second factor with respect to causal 15 inference is the strength of association; correct? 16 A. Yes. 17 Q. And as to that factor, unlike temporality, 18 it is not a prerequisite to drawing causal inference; 19 correct? 20 A. Well it helps to -- to establish that the 21 association is temp -- is -- is in fact causal because 22 otherwise it could easily be confounded with something 23 else. 24 Q. It helps, but it is not required as it is in 25 temporality; correct?</p>	<p style="text-align: right;">Page 345</p> <p>1 sure what you're -- 2 Q. Okay. 3 A. -- what you're saying. 4 Q. Is the association measured by the odds 5 ratio? 6 A. The magnitude of association, yes. 7 Q. Yes. So with respect to a number such as 8 3.8, that signifies the magnitude of the association 9 as reported in McGovern. 10 A. That -- that -- that is a point estimate of 11 magnitude -- 12 Q. Okay. 13 A. -- of association, yes. 14 Q. Okay. And that's different than a simple 15 determination of causation. 16 A. Yes. It's, of course, not just the point 17 estimate, -- 18 Q. Yes. 19 A. -- it's the precision of the estimate, so 20 you have to take into account the confidence interval 21 as well. 22 Q. An odds ratio of less than two can show 23 causation; correct? 24 A. It -- it might, yes. 25 Q. Yes.</p>

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<p style="text-align: right;">Page 346</p> <p>1 And you report that the odds ratio with 2 respect to Albrecht 10 using Fisher's exact is 2.76; 3 correct? 4 A. Yes. 5 Q. You also report that the odds ratio when 6 applying one additional infection in each arm of the 7 study, according to Mr. Reed's testimony, results in 8 an odds ratio of 2.89; correct? 9 A. I think so. 10 Q. Footnote one of your report. 11 A. I think that's right. I presume -- 12 Well 2.886 actually I think it is. Yes. 13 Q. That's -- 14 Oh, my apologies. I said 2.89. 15 With respect to when you control for the 16 thromboprophylaxis using Albrecht Exhibit 10, the odds 17 ratio is 2.16; correct? 18 A. Yes, I think it's right. 19 Q. You did not report an odds ratio when only 20 controlling for the antibiotic; correct? 21 A. That's correct. 22 Q. Aside from when you controlled both 23 variables, all of the odds ratios that we just 24 discussed are above 2.0; correct? 25 A. All of those, yes.</p>	<p style="text-align: right;">Page 348</p> <p>1 okay to rely on one observational study -- 2 MR. GORDON: Same -- 3 Q. -- to prove causation? 4 MR. GORDON: Same objection. 5 A. I am not a lawyer, I've not studied law, so 6 I'm not -- I don't know what the -- what the 7 definitions are that are used. 8 Q. You didn't opine on that in your report; 9 correct? 10 A. No. No. 11 Q. Okay. With respect to the variable of 12 consistency, which is the third factor that both you 13 and Dr. Samet considered with respect to causal 14 inference, even inconsistent results do not rule out 15 causal nexus; correct? 16 MR. GORDON: Object to the form of the 17 question. 18 A. What do you -- 19 If they're inconsistent, then it -- it's 20 going -- going to make it more difficult to determine 21 that the association is -- is causal. 22 Q. But you can still draw a causal inference 23 even with inconsistent results. 24 MR. GORDON: Same objection. 25 A. It really depends on what -- what you're</p>
<p style="text-align: right;">Page 347</p> <p>1 Q. Okay. And as we've established, if an odds 2 ratio is above 2.0, that signifies a doubling of the 3 risk; correct? 4 A. For the point estimate. 5 Q. Okay. 6 A. That's -- 7 The precision of that estimate is obviously 8 also relevant. 9 Q. Yeah. And the Augustine 2007 paper reports 10 an odds ratio for the multi-center data above four; 11 right? I believe that's what it was. 12 A. That's what's reported, yes. 13 Q. Okay. 14 MR. SACCHET: Can I have a time check, Mr. 15 Stirewalt? 16 THE VIDEOGRAPHER: Six hours and 20 minutes 17 we've been going, forty minutes remaining. 18 Q. Are you aware of the difference in the legal 19 standard versus scientific standard for drawing causal 20 inference? 21 MR. GORDON: Objection, object to the form, 22 also lack of foundation. 23 A. I'm not -- I don't -- not sure what you're 24 asking. 25 Q. Do you know whether as a matter of law it's</p>	<p style="text-align: right;">Page 349</p> <p>1 looking at. I mean in the abstract I don't -- I have 2 a hard time of knowing exactly what you're talking 3 about. 4 Q. Do you agree with the statement provided in 5 The Reference Manual on Epidemiology that inconsistent 6 results do not necessarily rule out a causal nexus? 7 A. Yes. 8 Q. You disagree with that? 9 A. No, I would agree with that. 10 Q. You agree with that. 11 A. Yes. 12 Q. Okay. Are you aware of any inconsistent 13 results with respect to the Bair Hugger causing deep 14 joint infections? 15 A. I -- I'm not -- 16 I don't agree with the idea that it -- it -- 17 that the causality has been established. If what 18 you're asking for is consistency of the 19 association, -- 20 Q. I can rephrase. 21 A. -- that -- that's a little different. 22 That's -- certainly the -- 23 I mean basically what we have is the 24 Augustine paper and the McGovern paper. Those 25 published associations are -- are consistent.</p>

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<p style="text-align: right;">Page 350</p> <p>1 Q. So there are two studies and they're both 2 consistent; correct? 3 A. Those two studies agree with each other, 4 apparently. 5 Q. Are you aware of any other observational 6 studies that have been conducted that are inconsistent 7 with those two studies? 8 A. Those are the only studies that I'm aware of 9 that have been -- that -- that have compared Bair 10 Hugger and Hot Dog. 11 Q. Are you aware of any mechanistic studies 12 that have been published that are inconsistent with 13 the fact that the Bair Hugger increases the risk of 14 deep joint infection? 15 MR. GORDON: Object to the form of the 16 question. 17 A. These are the only two studies that I -- I 18 think I said that I know of that have looked at that 19 association -- 20 Q. Okay. 21 A. -- between use of the -- of -- the type of 22 warming device that was used and risk of infection -- 23 of deep infection. 24 Q. Are you aware of any studies regarding the 25 Bair Hugger that show the device does not increase the</p>	<p style="text-align: right;">Page 352</p> <p>1 A. -- that have looked at that. 2 Q. On what basis do you conclude, then, that 3 there is any consistency, if any, with respect to the 4 risk of infection posed by the Bair Hugger? 5 MR. GORDON: Object to the form of the 6 question. 7 A. I -- I mean I think what I was -- what I 8 said in my report is that there's -- 9 Well, at the time this was written -- 10 Q. One study, yeah. 11 A. -- there was one study. 12 Q. That no longer applies; correct? 13 A. There's -- there's now two. 14 Q. And you've just said that those two studies 15 are consistent. 16 A. Those two studies made the same mistakes and 17 they found similar magnitudes of association, so 18 that's -- 19 So now there is a consistency of two. 20 Q. Okay. So you're -- 21 A. Samet was talking about -- was comparing the 22 situation of Bair Hugger to cigarettes. 23 Q. Could you show me where he does that? 24 A. Oh -- 25 MR. GORDON: Did you mark Samet already?</p>
<p style="text-align: right;">Page 351</p> <p>1 amount of particles over the surgical site? 2 MR. GORDON: Object to the form of the 3 question, lack of foundation. 4 A. That does not -- 5 Q. Increase particles over the surgical site. 6 A. Well if you're talking about -- 7 You're reducing it then for particles. I 8 mean we -- we've talked about -- 9 Q. Yeah. I'm just asking just this question. 10 A. -- discussed all of that on the record -- 11 Q. Just this question. 12 A. -- and I'm -- 13 I mean there have been several studies that 14 have looked at particle distribution associated with 15 the -- with the -- with the use of Bair -- Bair 16 Hugger. 17 Q. The question is: Are you aware of any 18 studies that do not show an increase in particles over 19 the surgical site from the Bair Hugger? That's the 20 question. "Yes" or "no." 21 MR. GORDON: Same objection. 22 A. I have not -- haven't really investigated 23 that -- that field of how -- of what all the studies 24 are -- 25 Q. On what basis --</p>	<p style="text-align: right;">Page 353</p> <p>1 MR. SACCHET: Yeah, I did. Exhibit 3. 2 A. I mean he uses cigarettes -- he -- he talks 3 about cigarettes, and that's basically the -- the 4 analogy that he is using where he's looking at that 5 association. 6 Q. Where does he do that? 7 A. Okay. Exhibit 3. 8 Q. I can speed this up for you, Professor 9 Holford, and -- and show you the two places that Dr. 10 Samet references tobacco, outside of his history, in 11 uncovering the link between tobacco use and cancer, if 12 that would be helpful. 13 A. Okay. 14 Q. On page 10, Dr. Samet says in the second -- 15 or the first full paragraph, about halfway through, 16 "For example, observational designs were used in 17 linking cigarette smoking to lung cancer, as some 18 people were either current or former smokers and 19 others had never smoked. Two basic designs were used; 20 the case-control study..." And he goes on to 21 explain -- 22 A. Uh-huh. 23 Q. -- those types of studies; correct? 24 A. Yes. 25 Q. That's one example.</p>

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<p style="text-align: right;">Page 354</p> <p>1 A. Yeah.</p> <p>2 Q. The second example is on page 11, in the</p> <p>3 third paragraph, in the last sentence, which says,</p> <p>4 "These arguments are the typical general claims made</p> <p>5 by those seeking alternative explanations for an</p> <p>6 association, and reach back to the strategies employed</p> <p>7 for decades by the tobacco industry," citing Proctor,</p> <p>8 2012 and Samet and Burke, 2001; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Are you aware of any other references to</p> <p>11 tobacco that Dr. Samet makes outside of the first</p> <p>12 three or four pages of the report which describes his</p> <p>13 background?</p> <p>14 A. Well I mean he --</p> <p>15 In this part of his report he is, I think,</p> <p>16 using tobacco as -- I mean it's under the section</p> <p>17 entitled "Evidence Synthesis and Findings on</p> <p>18 Causation."</p> <p>19 Q. Okay.</p> <p>20 A. So this is forming the basis that he's using</p> <p>21 for his justification of causation.</p> <p>22 Q. Where does he link the causation in tobacco</p> <p>23 to causation with the Bair Hugger? Where is that</p> <p>24 express link in this report?</p> <p>25 A. Well no, the point is not that he's -- that</p>	<p style="text-align: right;">Page 356</p> <p>1 regarding the incidence of cancer with respect to</p> <p>2 tobacco use, along with being an associate editor of</p> <p>3 the 1986 report to the Surgeon General. Are you aware</p> <p>4 of any other statement?</p> <p>5 MR. GORDON: Well -- well great, counsel,</p> <p>6 then you have all you need to know about your views.</p> <p>7 MR. SACCHET: Okay.</p> <p>8 MR. GORDON: If you want to know Dr.</p> <p>9 Holford's views, he's not going to rely on your</p> <p>10 representation of your views, he's going to go through</p> <p>11 the document and --</p> <p>12 Q. Sitting here today, do you have any</p> <p>13 recollection of any other statements that Dr. Samet</p> <p>14 has made linking the use of tobacco and the incidence</p> <p>15 of cancer to the use of the Bair Hugger and deep joint</p> <p>16 infection, sitting here right now?</p> <p>17 MR. GORDON: If you want him to answer that</p> <p>18 question, he will go through the report. If you don't</p> <p>19 want --</p> <p>20 MR. SACCHET: You just want me to do that,</p> <p>21 Corey, to use the rest of the time, which I'm not</p> <p>22 going to do.</p> <p>23 MR. GORDON: No. If you don't want a -- if</p> <p>24 you don't want an answer to the question, withdraw it</p> <p>25 and move on.</p>
<p style="text-align: right;">Page 355</p> <p>1 those two are --</p> <p>2 He's using tobacco, the experience with</p> <p>3 tobacco in showing the causal association with tobacco</p> <p>4 and -- as I understand it, to try to argue that</p> <p>5 there's a causal association between a warming device</p> <p>6 and the risk of in -- of deep infection.</p> <p>7 Q. So those two sentences in the 17-page report</p> <p>8 in your view show that Dr. Samet is linking tobacco to</p> <p>9 the Bair Hugger.</p> <p>10 A. Well it's not just those --</p> <p>11 MR. GORDON: No, no, no. Take -- take the</p> <p>12 time and go through it page by page and -- and --</p> <p>13 and --</p> <p>14 MR. SACCHET: We don't have time for that.</p> <p>15 MR. GORDON: Well then -- no. Then you're</p> <p>16 not going to just tell him what you've decided are the</p> <p>17 only two sentences and -- and -- and then get him to</p> <p>18 say -- to agree that those are the only two sentences.</p> <p>19 Q. Do you have a recollection to the contrary?</p> <p>20 I've gone through this report and I have made a great</p> <p>21 effort to isolate those two sentences that are the</p> <p>22 only two in my view that exist outside of the</p> <p>23 background section of this report in which Dr. Samet</p> <p>24 describes that he was a senior scientific editor of</p> <p>25 both the 2004 and 2014 report to the Surgeon General</p>	<p style="text-align: right;">Page 357</p> <p>1 Q. I'm asking right now: Sitting here today,</p> <p>2 are you aware of any other statements?</p> <p>3 MR. GORDON: I'm not going to let him answer</p> <p>4 that question --</p> <p>5 MR. SACCHET: You're going to instruct him</p> <p>6 not to answer?</p> <p>7 MR. GORDON: Yeah, I'm going to instruct him</p> <p>8 not to answer.</p> <p>9 MR. SACCHET: Okay. Noted for the record.</p> <p>10 I'll move on.</p> <p>11 MR. GORDON: If you want him to answer the</p> <p>12 question, he will go through the report and -- and</p> <p>13 answer it.</p> <p>14 Q. Do you agree with Dr. Borak that the</p> <p>15 particles are relevant to determining the coherency of</p> <p>16 the scientific evidence to draw a causal inference?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, lack of foundation, mischaracterizes the</p> <p>19 evidence, assumes facts not in evidence.</p> <p>20 THE REPORTER: We have 25 minutes left.</p> <p>21 A. What was the question again? I -- I don't</p> <p>22 understand --</p> <p>23 Q. Do you agree with Dr. Borak that studies</p> <p>24 involving particles are relevant to the factor of</p> <p>25 coherency under the Bradford-Hill criteria?</p>

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<p style="text-align: right;">Page 358</p> <p>1 MR. GORDON: Same objection.</p> <p>2 A. I haven't seen the -- the Borak report, as</p> <p>3 I --</p> <p>4 Q. I'm not asking you whether you've seen it,</p> <p>5 I'm asking whether you agree with Dr. Borak.</p> <p>6 MR. GORDON: Well you're assuming that</p> <p>7 you've --</p> <p>8 A. Well then how can I --</p> <p>9 MR. GORDON: -- accurately characterized</p> <p>10 what he said. He -- he -- he lacks foundation,</p> <p>11 counsel, he doesn't know what Dr. Borak said. If you</p> <p>12 want to ask him if he agrees generally with his --</p> <p>13 with whatever statement, you can ask him, but if</p> <p>14 you're going to pin it on Dr. Borak, he doesn't have a</p> <p>15 foundation to respond to that because he hasn't read</p> <p>16 it.</p> <p>17 Q. Do you disagree with this statement, "The</p> <p>18 particle count studies might contribute to coherence?"</p> <p>19 A. I -- I would need to get more of the</p> <p>20 background of what that statement is -- is --</p> <p>21 I mean you're taking one sentence out of --</p> <p>22 of a whole report.</p> <p>23 Q. Did you talk to Borak about your report?</p> <p>24 A. No.</p> <p>25 Q. Did you talk to Dr. Borak about his report?</p>	<p style="text-align: right;">Page 360</p> <p>1 mean we were covering different parts of the -- parts</p> <p>2 of the question, and so he's looking at -- he --</p> <p>3 He is considering different issues than what</p> <p>4 I considered.</p> <p>5 Q. Well what did you talk about on May 19th?</p> <p>6 A. Oh. You want me to generate minutes of the</p> <p>7 meeting? Which I didn't at the -- at the time.</p> <p>8 We were talking generally about -- about</p> <p>9 basically how we -- what the issues were that we</p> <p>10 would -- we would consider in our separate reports.</p> <p>11 Q. And were there any issues with respect to</p> <p>12 those views that either one of you were concerned</p> <p>13 about?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. What -- what are you asking? I don't</p> <p>17 understand the question.</p> <p>18 Q. Were there any topics of conversation that</p> <p>19 you were not comfortable with answering without</p> <p>20 talking to Dr. Borak?</p> <p>21 A. Not -- not in --</p> <p>22 Not that I was looking at in my report, no.</p> <p>23 Q. Okay. Were there any topics of conversation</p> <p>24 that questioned whether the Bair Hugger does in fact</p> <p>25 increase the rate of infection in deep joint</p>
<p style="text-align: right;">Page 359</p> <p>1 A. No.</p> <p>2 Q. You didn't meet with Dr. Borak on May 19th</p> <p>3 in Washington, DC?</p> <p>4 A. I did, but the --</p> <p>5 Neither one of us, I think, had written a</p> <p>6 report to that point.</p> <p>7 Q. Did you talk about the substance of the</p> <p>8 report prior to writing the report?</p> <p>9 A. Of our report?</p> <p>10 Q. Yeah.</p> <p>11 A. We didn't discuss our own reports. Our</p> <p>12 reports are our reports.</p> <p>13 Q. What did you talk about at the May 19th</p> <p>14 meeting?</p> <p>15 A. Generally talked about how --</p> <p>16 I mean we're in different fields, --</p> <p>17 Q. I understand.</p> <p>18 A. -- I mean, and so --</p> <p>19 Q. Is your field specific to statistics and Dr.</p> <p>20 Borak's is specific to epidemiology?</p> <p>21 A. That's more of the division it would be --</p> <p>22 it would be, I would say.</p> <p>23 Q. Was the decision that you would opine on</p> <p>24 statistics and Dr. Borak would respond on epi?</p> <p>25 A. Well there is some -- some overlap, but I</p>	<p style="text-align: right;">Page 361</p> <p>1 infections?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question.</p> <p>4 A. What was the question again?</p> <p>5 Q. Was there any conversation as to whether the</p> <p>6 Bair Hugger does in fact increase the rate of deep</p> <p>7 joint infection?</p> <p>8 A. I mean there was general discussion about</p> <p>9 what the -- what the association was and what --</p> <p>10 what -- what the state of the evidence was on -- on</p> <p>11 that association.</p> <p>12 Q. Okay. Is it true that you decided that Dr.</p> <p>13 Borak would be primarily responsible for the causal</p> <p>14 inferences based on epidemiology and you would be</p> <p>15 primarily responsible with respect to the statistical</p> <p>16 application and reanalysis of the McGovern data?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question, also lack of foundation.</p> <p>19 A. I'm not sure what you're asking. I --</p> <p>20 Q. Did Dr. Borak ask you to help with drafting</p> <p>21 a report or did 3M ask you?</p> <p>22 A. 3M.</p> <p>23 Q. They approached you independently of Dr.</p> <p>24 Borak?</p> <p>25 A. I think they may have gotten my name from</p>

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<p style="text-align: right;">Page 362</p> <p>1 Dr. Borak, but --</p> <p>2 Q. Okay.</p> <p>3 A. -- we did not discuss our reports --</p> <p>4 Q. Okay.</p> <p>5 A. -- together.</p> <p>6 Q. Getting back to the question: Do you have</p> <p>7 any reason to doubt Dr. Borak's statement that</p> <p>8 particles might contribute to the question of</p> <p>9 coherency under the Bradford-Hill criteria?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question, incomplete hypothetical, also lack of</p> <p>12 foundation.</p> <p>13 A. As I say, I haven't read his report, so I</p> <p>14 would have to read his report and study his report to</p> <p>15 know exactly what he's saying. I don't -- I don't</p> <p>16 know --</p> <p>17 You're taking that sentence out of his</p> <p>18 report, and you'll have to give me time to read the</p> <p>19 report and to -- to -- to comment on it.</p> <p>20 Q. Well let's look at the paragraph that he</p> <p>21 discusses because it's three sentences long and I</p> <p>22 don't think --</p> <p>23 It's going to illuminate the issue.</p> <p>24 (Exhibit 29 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 364</p> <p>1 Q. Okay. Well in this section of his report,</p> <p>2 if you turn back a couple pages, on page 20 we see the</p> <p>3 Samet opinion, correct, on the top of the page 20?</p> <p>4 A. Right. Yes.</p> <p>5 Q. And then paragraph 61 says "Strength of</p> <p>6 Association," correct, as the --</p> <p>7 A. Yeah.</p> <p>8 Q. -- subject of that paragraph.</p> <p>9 A. Uh-huh.</p> <p>10 Q. Paragraph 65 has the consistency of the data</p> <p>11 as the topic of that paragraph, and then the</p> <p>12 paragraphs that follow that relate to consistency,</p> <p>13 correct, because paragraph 70 is entitled "Coherence."</p> <p>14 A. Oh, I see. So -- okay. So he's talking</p> <p>15 about consistency. So I wasn't understanding what you</p> <p>16 were saying for that.</p> <p>17 Yeah, it says it "might contribute."</p> <p>18 Q. You disagree with that statement.</p> <p>19 A. It's a pretty vague statement, isn't it? I</p> <p>20 don't know. It might. It might or it might not.</p> <p>21 Q. Okay. Do you disagree with it?</p> <p>22 Might it?</p> <p>23 A. Might it? It might.</p> <p>24 Q. Okay.</p> <p>25 MR. SACCHET: Where are we at?</p>
<p style="text-align: right;">Page 363</p> <p>1 MR. GORDON: Page?</p> <p>2 BY MR. SACCHET:</p> <p>3 Q. If you could please turn to page 22, and</p> <p>4 I'll read the isolated sentence and then we can turn</p> <p>5 back to page 21 and read the preceding sentences.</p> <p>6 A. Page 22?</p> <p>7 Q. Yes.</p> <p>8 A. These are references.</p> <p>9 Q. You might be -- you might be looking at page</p> <p>10 22 of the references as opposed to page 22 of the</p> <p>11 report itself.</p> <p>12 A. Oh, I'm sorry. This is --</p> <p>13 I guess it's actually his CV. Okay. Sorry.</p> <p>14 Q. At the top of page 22 it says, "However, as</p> <p>15 discussed below, the particle count studies might</p> <p>16 contribute to coherence." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. I'm happy to read the preceding</p> <p>19 sentence if that provides context for you. We can</p> <p>20 look at the subsequent statements if that provides</p> <p>21 context. What would be helpful to you?</p> <p>22 A. "...might contribute to co" --</p> <p>23 "...might contribute to coherence," what</p> <p>24 does he mean by that? I'm not sure --</p> <p>25 Oh.</p>	<p style="text-align: right;">Page 365</p> <p>1 THE VIDEOGRAPHER: We have 20 -- 21 minutes</p> <p>2 remaining.</p> <p>3 Q. With respect to making causal inferences,</p> <p>4 mechanistic studies may be helpful; correct?</p> <p>5 MR. GORDON: Object to the form of the</p> <p>6 question.</p> <p>7 A. What type of mechanistic studies are you --</p> <p>8 are you indicating?</p> <p>9 Q. So a study or a document that shows the</p> <p>10 biological plausibility or the mechanism of infection</p> <p>11 by which either a drug or a device or --</p> <p>12 A. Okay.</p> <p>13 Q. -- some entity might result in an increased</p> <p>14 outcome at issue.</p> <p>15 A. That can help, yes.</p> <p>16 Q. That can help.</p> <p>17 A. Yes.</p> <p>18 Q. And in the event of two products, for</p> <p>19 example, --</p> <p>20 A. Uh-huh.</p> <p>21 Q. -- would it be helpful if one particular</p> <p>22 product, albeit a different product, had the same</p> <p>23 mechanism of infection as a different product?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>

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<p style="text-align: right;">Page 366</p> <p>1 A. I guess I would have to know exactly what 2 the -- what -- what was -- what -- what you're -- what 3 was involved in the two products and which was -- 4 Q. So in the event that there is one product 5 like the Bair Hugger where Dr. Samet opines that one 6 of the causal mechanisms is the disruption of airflow 7 currents in the operating room that then deposit 8 bacteria on the surgical site, if that's the mechanism 9 of the Bair Hugger for the sake of an example -- 10 Do you understand? 11 A. Okay. 12 Q. -- and if there were another product that 13 involved the same mechanism of infection of creating 14 currents of air in an operating room that caused 15 bacteria to be deposited at the surgical site, those 16 are the same mechanisms of infection; correct? 17 A. Uh-huh. 18 Q. But they're different products, for example. 19 A. Okay. 20 Q. Because the mechanism is the same, would 21 that contribute to coherency of drawing an inference 22 about causation? 23 MR. GORDON: Object to the form of the 24 question, incomplete hypothetical, assumes facts not 25 in evidence, lack of foundation.</p>	<p style="text-align: right;">Page 368</p> <p>1 A. I was not separately studying the -- the SSI 2 and -- and DJI, yeah. 3 Q. Okay. But with respect to the two devices 4 that share the same exact mechanism of infection that 5 would both increase the risk of infection, that would 6 be helpful in determining whether there was biological 7 plausibility or coherency to whether there was an 8 increased risk of infection; correct? 9 MR. GORDON: Same objection. 10 A. It -- it -- it could be. 11 Q. Okay. 12 A. I don't know. 13 Q. Okay. 14 A. It depends on the details. 15 (Exhibit 30 was marked for 16 identification.) 17 BY MR. SACCHET: 18 Q. This is a document from the CDC; correct, 19 Dr. Holford? 20 A. It appears to be. 21 Q. Are you familiar with HICPAC? 22 A. I'm not familiar with it, no. 23 Q. Okay. If you could please turn to page 24 24 of that document, there is a title that says 25 "Nontuberculosis Mycobacterium Infections Associated</p>
<p style="text-align: right;">Page 367</p> <p>1 A. Well it -- I mean I think if -- if -- 2 It depends a lot, I think, on what the -- 3 what the outcome is on -- on the -- the study that 4 you're -- 5 Q. Same outcome. Let's say -- 6 A. Infection? 7 Q. -- infection and that -- 8 A. Deep infection? 9 Q. -- that's the one you've always been worried 10 about. 11 A. Okay. So if you're looking at a deep 12 infection, if that is the outcome that you're 13 measuring with these -- with these two different 14 devices, then -- then I think it would be helpful. 15 Q. What if it was SSI versus DJI? 16 MR. GORDON: Same objection. 17 A. It -- there it -- 18 I mean when you start getting away from it, 19 then you really have to get into the details of what 20 it is that -- that you're -- what -- what it is you're 21 looking at and where the -- where the potential 22 differences could be. 23 Q. You need to look into those details with 24 respect to whether the SSI intervention measures have 25 an impact on deep joint infection; correct?</p>	<p style="text-align: right;">Page 369</p> <p>1 With Heater-Cooler Devices." Do you see that? 2 A. Yes. 3 Q. Okay. And heater-cooler devices are not the 4 same as Bair Huggers; correct? 5 A. I don't know what devices they're talking 6 about. 7 Q. Okay. The first sentence of text says, "Dr. 8 Perz reviewed points about Nontuberculosis 9 Mycobacterium and infections associated with 10 heater-cooler devices;" correct? 11 A. Yes. 12 Q. And this is talking about a device, whether 13 or not you know that it's the same as the Bair Hugger 14 or not; correct? 15 MR. GORDON: Object to the form of the 16 question, lack of foundation. 17 Q. Does -- does this say that there's a device 18 that they're discussing? 19 A. There is a device they're discussing. 20 Q. Okay. 21 A. I don't know -- 22 I know nothing about it, -- 23 Q. Yeah. 24 A. -- the device. 25 Q. I understand that.</p>

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<p style="text-align: right;">Page 370</p> <p>1 On page 25 in the second paragraph --</p> <p>2 A. Yeah.</p> <p>3 Q. -- it says, "Two fans are present in the</p> <p>4 heater-cooler."</p> <p>5 A. Uh-huh.</p> <p>6 Q. And it says, "This design is typical for</p> <p>7 this class of device. One fan cools the device's</p> <p>8 internal components, and another, larger fan draws air</p> <p>9 into the machine." Correct?</p> <p>10 A. Yes, that's what it says. Yeah.</p> <p>11 Q. Do you know that the Bair Hugger draws air</p> <p>12 into the machine so it warms patients through the hose</p> <p>13 and into the blanket?</p> <p>14 A. I -- I don't know very much about the de --</p> <p>15 I -- I think that's what it does -- does. I</p> <p>16 don't know a lot of detail about how the -- how the</p> <p>17 Bair Hugger works.</p> <p>18 Q. You don't know a lot of details about how</p> <p>19 the Bair Hugger works?</p> <p>20 A. No.</p> <p>21 Q. Okay. On page 26 there are five bullets</p> <p>22 listed there. Do you see them?</p> <p>23 A. Yes.</p> <p>24 Q. And the third one is, "Direct the exhaust</p> <p>25 from the device away from the sterile field." Do you</p>	<p style="text-align: right;">Page 372</p> <p>1 A. It -- I mean it -- it sort of co --</p> <p>2 coincides with a lot of the concern of what we've been</p> <p>3 talking about today.</p> <p>4 Q. It does; correct?</p> <p>5 A. It's really --</p> <p>6 MR. GORDON: Same objections.</p> <p>7 A. Well I think that was the bas -- basic --</p> <p>8 the -- the purpose of the bubble study and whatnot, is</p> <p>9 to consider --</p> <p>10 Q. Yeah.</p> <p>11 A. -- particles that were distributed in the</p> <p>12 operating room.</p> <p>13 Q. So this is describing a similar concern</p> <p>14 based on the mechanism of infection; correct?</p> <p>15 MR. GORDON: Same objection.</p> <p>16 A. Well it doesn't say why. I mean I -- it</p> <p>17 just --</p> <p>18 Q. One of -- one of the mechanisms is that</p> <p>19 blowing air in the operating room might create</p> <p>20 convection currents that deposit bacteria at the</p> <p>21 surgical site; correct?</p> <p>22 MR. GORDON: Same objections.</p> <p>23 A. I --</p> <p>24 Q. According to Dr. Samet.</p> <p>25 A. Well if it's Dr. Samet, I mean quote Dr.</p>
<p style="text-align: right;">Page 371</p> <p>1 see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And then on the subsequent page, page</p> <p>4 27, in the last paragraph it says, "The heater-cooler</p> <p>5 unit appears to be harmless from an infection</p> <p>6 perspective, but the water overflow -- overflow bottle</p> <p>7 is likely rarely, if ever, sanitized and is situated</p> <p>8 in front of a fan. Nothing that blows air should be</p> <p>9 in the operating theater, if possible." Do you see</p> <p>10 that?</p> <p>11 A. Yes.</p> <p>12 Q. Do you know why they're concerned about</p> <p>13 things blowing air in the operating room?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question, lack of foundation, it mischaracterizes the</p> <p>16 evidence.</p> <p>17 A. I mean I -- I --</p> <p>18 This is the first I read this, I -- I've</p> <p>19 seen this article. I -- it's -- it's -- it's really</p> <p>20 not my -- my -- not my area.</p> <p>21 Q. You've seen this article?</p> <p>22 A. No, I have not seen it.</p> <p>23 Q. You have not seen it.</p> <p>24 A. That's what I said.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 373</p> <p>1 Samet. It's not --</p> <p>2 That's not my area. I mean we've already</p> <p>3 established what his area is --</p> <p>4 Q. Okay.</p> <p>5 A. -- and this is an area that he feels</p> <p>6 comfortable in and that -- and has -- has -- has done</p> <p>7 work in, and this is not the area --</p> <p>8 Q. You don't feel comfortable in this area.</p> <p>9 A. It's not an area that I -- that I work</p> <p>10 in, --</p> <p>11 Q. Okay.</p> <p>12 A. -- no.</p> <p>13 Q. And so you're unclear about what the</p> <p>14 mechanism of infection that is the issue with respect</p> <p>15 to blowing air in the operating theater; is -- is</p> <p>16 that -- is that your testimony?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 A. It's --</p> <p>20 I mean the authors of this report are</p> <p>21 obviously concerned about blowing -- you know, blowing</p> <p>22 air over water that's -- water that's infected.</p> <p>23 Q. Uh-huh.</p> <p>24 A. I don't know enough about the mechanism of</p> <p>25 the Bair Hugger --</p>

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<p style="text-align: right;">Page 374</p> <p>1 Q. Yeah.</p> <p>2 A. -- to know exactly what is --</p> <p>3 Is there a pool of water in the Bair Hugger</p> <p>4 that it -- that it's blowing air over?</p> <p>5 Q. Okay.</p> <p>6 A. I don't know.</p> <p>7 Q. So you've opined about whether one can draw</p> <p>8 a causal inference as to whether the Bair Hugger</p> <p>9 increases the risk of infection, but you don't</p> <p>10 understand the ways in which the Bair Hugger might in</p> <p>11 fact result in an increase in infection.</p> <p>12 MR. GORDON: Object to the form of the</p> <p>13 question, misstates his testimony.</p> <p>14 A. I think -- I think that's not -- not an</p> <p>15 accurate description of what -- what I've -- what I've</p> <p>16 been saying. I was looking at the -- the evidence for</p> <p>17 a causal -- a causal association --</p> <p>18 Q. Uh-huh.</p> <p>19 A. -- and does -- that has in -- that has</p> <p>20 basically involved looking at what the -- the design</p> <p>21 and the estimates of effect that were known to me</p> <p>22 at the -- at the time that I did that -- did that</p> <p>23 analysis.</p> <p>24 Q. And that's it.</p> <p>25 A. And that's basically what I was drawing my</p>	<p style="text-align: right;">Page 376</p> <p>1 specifically to these devices. I was primarily</p> <p>2 concentrating on the studies that had been done on the</p> <p>3 epidemiology.</p> <p>4 Q. And those studies are the McGovern study and</p> <p>5 the Augustine study, which are the only two</p> <p>6 epidemiologic studies on the risk of infection from</p> <p>7 the Bair Hugger to deep joint infection; correct?</p> <p>8 A. For the Bair -- for the Bair Hugger effect,</p> <p>9 the Bair Hugger/Hot Dog comparison, those were the --</p> <p>10 basically the studies that I was comparing.</p> <p>11 MR. SACCHET: Okay. We're going to look at</p> <p>12 one more document. Maybe two, but --</p> <p>13 (Exhibit 31 was marked for</p> <p>14 identification.)</p> <p>15 BY MR. SACCHET:</p> <p>16 Q. This is another document from the CDC;</p> <p>17 correct?</p> <p>18 MR. GORDON: Objection, lack of foundation.</p> <p>19 THE REPORTER: We have eight minutes left.</p> <p>20 Q. Does the title page of this document,</p> <p>21 professor, show the CDC's logo on it?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And if you could please turn to page</p> <p>24 12 of the document, it states "FDA Device Updates:</p> <p>25 Flexible Endoscopes and Heater Coolers;" correct?</p>
<p style="text-align: right;">Page 375</p> <p>1 con -- conclusions are about -- about causal</p> <p>2 inference.</p> <p>3 Q. Okay.</p> <p>4 A. It was basically the strength --</p> <p>5 Q. Uh-huh.</p> <p>6 A. -- in terms of not only the magnitude of the</p> <p>7 effect, but in terms of the design that was used</p> <p>8 and -- to -- to find those -- those associations and</p> <p>9 whether that is -- the strength of that evidence is --</p> <p>10 was enough to demonstrate a causal -- a causal</p> <p>11 association.</p> <p>12 Q. Do you agree with the statement from The</p> <p>13 Reference Manual on Statistics that "In the end,</p> <p>14 deciding whether associations are causal typically is</p> <p>15 not a matter of statistics alone, but also rests on</p> <p>16 scientific judgment?"</p> <p>17 A. Yes.</p> <p>18 Q. You've only considered the statistical</p> <p>19 aspects; correct?</p> <p>20 A. Well I tried to consider the -- the other</p> <p>21 aspects of -- of the -- of the study as well.</p> <p>22 Q. You said you have no expertise and have not</p> <p>23 delved into the literature as to those additional</p> <p>24 topics; correct?</p> <p>25 A. Of the associated -- of things related</p>	<p style="text-align: right;">Page 377</p> <p>1 A. Yes.</p> <p>2 Q. Okay. If you could turn to page 15 of the</p> <p>3 document, there are a number of bullet points;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And the fourth one down says, "The</p> <p>7 orientation of the vent(s) on the devices may or may</p> <p>8 not direct the fan exhaust toward the patient or the</p> <p>9 sterile field. The exhaust from cooling fans may also</p> <p>10 play a role in the airflow within the OR, possibly</p> <p>11 facilitating movement of the aerosolized NTM into the</p> <p>12 sterile field." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Is that the same mechanism of infection that</p> <p>15 Dr. Samet described in his report?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, lack of foundation, assumes facts not</p> <p>18 evidence, mischaracterizes the testimony.</p> <p>19 A. I -- I don't recall the detail of how --</p> <p>20 what Dr. Samet's description was on -- on -- on the --</p> <p>21 on the -- on devices used.</p> <p>22 Q. One of the issues in this litigation that</p> <p>23 was discussed in the McGovern study, which you are</p> <p>24 aware of, is that the Bair Hugger might generate</p> <p>25 convection currents that results in increased</p>

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<p style="text-align: right;">Page 378</p> <p>1 particles over the surgical site; correct?</p> <p>2 A. Yes. Yes.</p> <p>3 Q. This bullet says that "The exhaust from</p> <p>4 cooling fans may also play a role in the airflow</p> <p>5 within the OR, possibly facilitating movement of the</p> <p>6 aerosolized NTM into the sterile field." Do you see</p> <p>7 that?</p> <p>8 MR. GORDON: Objection, asked and answered.</p> <p>9 Q. You've seen it.</p> <p>10 Does that describe a similar mechanism of</p> <p>11 moving particles or bacteria to the sterile field?</p> <p>12 MR. GORDON: Well wait, wait, wait. You</p> <p>13 started out with talking about convection currents,</p> <p>14 now you're changing gears. What -- what are you</p> <p>15 asking him?</p> <p>16 Q. I'm asking: One of the mechanisms of</p> <p>17 infection described in the McGovern study is the</p> <p>18 movement of particles from air currents generated by</p> <p>19 the Bair Hugger; correct?</p> <p>20 MR. GORDON: Well before you said convection</p> <p>21 currents, not --</p> <p>22 MR. SACCHET: Okay.</p> <p>23 MR. GORDON: You say you're changing that</p> <p>24 now?</p> <p>25 MR. SACCHET: I am.</p>	<p style="text-align: right;">Page 380</p> <p>1 comment on it, I object on the grounds of lack of</p> <p>2 foundation.</p> <p>3 Q. Does this describe a similar mechanism of</p> <p>4 infection as noted by McGovern et al in the study that</p> <p>5 you have reviewed?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question, also lack of foundation, also</p> <p>8 mischaracterizes the evidence.</p> <p>9 A. I'm not sure it --</p> <p>10 It's un -- it's unclear. I mean just that</p> <p>11 sentence, I can't figure out -- I -- I -- I'm not --</p> <p>12 unclear as to whether -- how this relates to what</p> <p>13 McGovern is saying.</p> <p>14 Q. Did you try to shore up your</p> <p>15 misunderstanding or questions about that statement?</p> <p>16 A. Well I mean you just -- you just showed me</p> <p>17 this, --</p> <p>18 Q. Okay. So you -- you didn't investigate --</p> <p>19 A. -- so how could I --</p> <p>20 Q. You didn't investigate this.</p> <p>21 A. Not when --</p> <p>22 No. I mean you asked me this question</p> <p>23 about --</p> <p>24 Q. You didn't know about it.</p> <p>25 A. -- a minute before. I didn't know about</p>
<p style="text-align: right;">Page 379</p> <p>1 MR. GORDON: Okay.</p> <p>2 MR. SACCHET: Yes.</p> <p>3 Q. That's correct.</p> <p>4 A. Okay.</p> <p>5 Q. And this bullet, which is from the CDC that</p> <p>6 we established, says that "The exhaust from cooling</p> <p>7 fans may also play a role in the airflow within the</p> <p>8 OR, possibly facilitating the movement of the</p> <p>9 aerosolized NTM into the sterile field;" correct?</p> <p>10 A. It possibly is.</p> <p>11 MR. GORDON: Objection, asked and answered.</p> <p>12 Q. Possibly?</p> <p>13 MR. GORDON: You read it right.</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 MR. GORDON: Are you asking him if he -- if</p> <p>17 he has any basis for --</p> <p>18 MR. SACCHET: No, I'm not, Corey.</p> <p>19 MR. GORDON: -- saying anything --</p> <p>20 commenting on that?</p> <p>21 MR. SACCHET: Please don't use the rest of</p> <p>22 my time. I'm not going to engage --</p> <p>23 MR. GORDON: Well I want -- I want to get an</p> <p>24 objection. I thought you were just, once again,</p> <p>25 reading the same sentence. If you're asking him to</p>	<p style="text-align: right;">Page 381</p> <p>1 this report, no.</p> <p>2 MR. SACCHET: Okay. I'm going to show you</p> <p>3 one other document.</p> <p>4 (Exhibit 32 was marked for</p> <p>5 identification.)</p> <p>6 BY MR. SACCHET:</p> <p>7 Q. This is a document bearing the Bates number</p> <p>8 3MBH0001 -- 1336; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Have you seen it before?</p> <p>11 A. No.</p> <p>12 Q. The top line says "CONFIDENTIAL - NOT FOR</p> <p>13 EXTERNAL DISTRIBUTION;" correct?</p> <p>14 A. Yes.</p> <p>15 Q. And then the bolded typeface says "Arizant</p> <p>16 forced-air warming and SSI prevention: Talking points</p> <p>17 for sales;" correct?</p> <p>18 A. Yes.</p> <p>19 Q. And it says "Our position." The first line</p> <p>20 is, "There is no evidence that forced-air warming</p> <p>21 (FAW) increases risk of surgical site infections</p> <p>22 (SSIs)...;" correct?</p> <p>23 A. That's what it says.</p> <p>24 Q. And there's a comment right next to it;</p> <p>25 correct?</p>

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<p style="text-align: right;">Page 382</p> <p>1 A. Yes.</p> <p>2 Q. And it says, "Actually, there is evidence</p> <p>3 that FAW use increases risk." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know who wrote that statement?</p> <p>6 A. No, I don't.</p> <p>7 Q. Do you know whether that statement was</p> <p>8 written by a 3M employee?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question, lack of foundation.</p> <p>11 A. I've never seen this document before, so I</p> <p>12 have no idea.</p> <p>13 Q. Are you surprised that this statement was</p> <p>14 made in a document that's confidential regarding</p> <p>15 Arizant talking points on SSI prevention?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, lack of foundation, misstates --</p> <p>18 mischaracterizes the evidence.</p> <p>19 A. I don't --</p> <p>20 I mean I know basically nothing about this</p> <p>21 document.</p> <p>22 Q. You've never seen it before.</p> <p>23 A. I've never seen it before.</p> <p>24 Q. Okay. Did you look at any documents that</p> <p>25 had a 3M Bates number on it, like this in the bottom</p>	<p style="text-align: right;">Page 384</p> <p>1 provided by 3M with respect to the use of the Bair</p> <p>2 Hugger at particular hospitals in the NHS and that</p> <p>3 those documents were not cited in his report, I'm</p> <p>4 leaving the deposition open.</p> <p>5 THE REPORTER: Off the record, please.</p> <p>6 (Deposition concluded.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 383</p> <p>1 right-hand corner, as part of your review?</p> <p>2 A. Any documents that had --</p> <p>3 Q. That had a Bates number bearing the prefix</p> <p>4 3MBH.</p> <p>5 A. I don't recall. I -- al -- although I don't</p> <p>6 know --</p> <p>7 I didn't look carefully at that Bates number</p> <p>8 on all of the documents. I don't recall that.</p> <p>9 Q. Were any internal 3M documents provided to</p> <p>10 you as part of your review of the evidence in this</p> <p>11 case?</p> <p>12 A. No.</p> <p>13 Q. Did you meet with any people from 3M with</p> <p>14 respect to preparing your report?</p> <p>15 A. No, I did not.</p> <p>16 MR. SACCHET: Okay. I will reserve the rest</p> <p>17 of my time.</p> <p>18 THE REPORTER: Off the record, please.</p> <p>19 (Discussion off the record.)</p> <p>20 MR. GORDON: We'll read -- we'll read and</p> <p>21 sign.</p> <p>22 MR. SACCHET: I'd like to make one note.</p> <p>23 THE REPORTER: Let's go back on the record.</p> <p>24 MR. SACCHET: To the extent that Dr. Holford</p> <p>25 has noted in his report that he reviewed documents</p>	<p style="text-align: right;">Page 385</p> <p>1 C E R T I F I C A T E</p> <p>2 I, Richard G. Stirewalt, hereby certify that</p> <p>3 I am qualified as a verbatim shorthand reporter, that</p> <p>4 I took in stenographic shorthand the deposition of</p> <p>5 THEODORE R. HOLFORD at the time and place aforesaid,</p> <p>6 and that the foregoing transcript is a true and</p> <p>7 correct, full and complete transcription of said</p> <p>8 shorthand notes, to the best of my ability.</p> <p>9 Dated at Deerwood, Minnesota, this 23rd day</p> <p>10 of July, 2017.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17 RICHARD G. STIREWALT</p> <p>18 Registered Professional Reporter</p> <p>19 Notary Public</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

C E R T I F I C A T E

I, THEODORE R. HOLFORD, hereby certify that
I have carefully read the foregoing transcript, and
that the same is a true and complete, full and correct
transcription of my deposition, except:

PAGE/LINE	CHANGE	REASON
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THEODORE R. HOLFORD
Deponent

Signed and sworn to before me this ____ day of
August, 2017.

Notary Public

EXHIBIT DX3

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

**Report of Jonathan Borak, MD, DABT
June 02, 2017**

I. Introduction

1. I am a Clinical Professor of Epidemiology & Public Health and Clinical Professor of Medicine at Yale University, a faculty member of the Yale Occupational and Environmental Medicine Program, and Adjunct Associate Professor of Medicine at The Johns Hopkins University. I am also President of Jonathan Borak & Company, a consulting firm in New Haven, Connecticut. My CV is attached at Exhibit A and a list of my previous deposition and trial testimony is attached at Exhibit B.

2. I received my B.A. with honors from Amherst College in 1968 and my M.D. from New York University in 1972. I am Board Certified in Internal Medicine, Preventive Medicine (Occupational Medicine) and Toxicology (American Board of Toxicology). I am a Fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, the Royal College of Physicians of Canada, the Academy of Toxicological Sciences, and the American Industrial Hygiene Association.

3. Among my Yale activities, I have directed and taught two required graduate-level courses (Principles of Toxicology and Principles of Risk Assessment) for nearly twenty years. I also lecture in a number of other graduate-level courses including occupational epidemiology, environmental exposure assessment, and environmental health. Included in this teaching are the interpretation of epidemiological data and inference of causation. From 2002-2010 I was Director of the Yale University Interdisciplinary Risk Assessment Forum. I also participate in the supervision and training of Fellows and other resident physicians in the Yale Occupational and Environmental Medicine Program.

4. I served as an elected Director of the American College of Occupational and Environmental Medicine (ACOEM) from 1999-2002 and as Chair of the ACOEM Council on Scientific Affairs from 1999-2012. I was a founding member of US EPA's National Advisory Committee to Develop Acute Exposure Guideline Levels for Hazardous Substances, a member of the National Research Council Committee on Toxicologic Assessment of Low-Level Exposures to Chemical Warfare Agents, a member of a National Institute of Environmental Health Sciences review panel on Partnerships for Environmental Public Health, and a member of an External Review Panel for the National Institute for Occupational Safety and Health. I was President of the Occupational and Environmental Medicine Association of Connecticut, President of the Connecticut College of Emergency Physicians, and Chairman of the Connecticut State Medical Society Committees on Preventive Medicine and on Emergency Medical Services.

5. I am a member of the Editorial Boards of Journal of Occupational and Environmental Medicine, Journal of Occupational and Environmental Hygiene, and

Occupational Medicine. I served as Associate Editor of OEM Report, as a member of the Editorial Board of the American Industrial Hygiene Association Journal, and currently serve as a peer reviewer for numerous medical and scientific publications.

6. I have written numerous books, monographs, book chapters, peer-reviewed articles and other publications on a range of topics in occupational medicine, toxicology, epidemiology, industrial hygiene and public health.

7. I have received numerous awards from ACOEM including: the President's Award in 1994, 2000 and 2008; the Adolph G. Kammer Merit in Authorship Award in 2003; the Robert A. Kehoe Award of Merit in 2004; and the George H. Gerchman Memorial Prize in 2005. I also received the Harriet Hardy Award from the New England College of Occupational and Environmental Medicine in 2012.

8. In the present matter, I was asked by Mr. Corey Gordon of Blackwell Burke to review expert reports, depositions and other materials concerning the use of forced air warming devices (FAW) (such as the Bair Hugger) during surgery and any associated risks of surgical site infections (SSI). I was also asked to review the expert report of Dr. Jonathan Samet and Dr. William Jarvis and, in light of these reports, to opine as to whether there is sufficient evidence to support the general proposition that use of the Bair Hugger (BH) during orthopedic surgery causes or contributes to increased rates of post-operative SSI in patients who undergo total hip and total knee arthroplasty procedures. My company, Jonathan Borak & Company, is compensated at a rate of \$550 per hour for my time in reviewing materials and preparing this report and \$600 per hour for testimony.

I offer my opinions herein to a reasonable degree of medical and scientific certainty.

9. Accordingly, I reviewed the expert reports and testimony listed below:

Expert Reports

Dr. Jonathan M. Samet	March 30, 2017
Dr. William R. Jarvis	signed but undated
Dr. Theodore Holford	June 1, 2017
Dr. Richard Wenzel	June 2, 2017

Deposition Transcripts and Exhibits

Mr. Mark Albrecht (Vol 1)	October 7, 2016
Mr. Mark Albrecht (Vol 2)	November 12, 2016
Dr. Scott Augustine	March 31, 2017
Dr. Andrew John Legg	December 1, 2016
Dr. Paul McGovern (Vol 1)	January 4, 2017
Dr. Paul McGovern (Vol 2)	January 5, 2017
Dr. Christopher Nachtshteim	November 29, 2016

Dr. Michael Reed

December 4, 2016

10. I also reviewed a large number of scientific reports related to surgical warming devices, operating room procedures, surgical complications and infections, and other related medical and scientific issues. Specific publications on which I rely are cited in my report.

II. The Samet Report

11. In his report, Dr. Samet embraced the “sufficient-component-cause model” as the methodological basis for his general causation opinion that use of BH during surgery increases the probability of deep joint infection. In particular, he proposed that use of BH increased the probability “compared to what that probability would have been, absent the utilization of the BH device during hip and knee arthroplasties”. He went on to state that there were actually two different comparisons to consider: a) use of BH versus no specific warming device; and b) use of BH compared to a non-FAW device.

11a. There is sufficient evidence that warming surgical patients to prevent hypothermia and maintain normothermia reduces rates of SSI, and thus the use of intraoperative warming has become a standard of current surgical care. For example, the following is a conclusion from the CDC’s *Guideline for the Prevention of Surgical Site Infection, 2017* (1):

“Maintain perioperative normothermia. (Category IA – strong recommendation; high to moderate-quality evidence)”

“High-quality evidence suggested a benefit of patient warming over no warming.”

Likewise, the World Health Organization recommends the use of warming devices in the operating room (2):

“The panel suggests the use of warming devices in the operating room and during the surgical procedure for patient body warming with the purpose of reducing SSI (conditional recommendation, moderate quality of evidence).”

In addition, published findings from two random control trials document that use of BH to maintain intraoperative normothermia reduced the risk of SSI (3;4). Moreover, I am not aware of any basis to propose that use of BH poses increased risks of surgical infection compared to “no specific warming device”.

Therefore, the hypothetical comparison of BH vs. no warming device is not relevant to the current dispute.

11b. The alternative comparison, whether use of BH results in increased rates of SSI compared to use of a non-FAW device, all other things being equal, is the central question here. That question is amenable to empirical assessment,

including whether there is sufficient evidence of a significant difference between the two methods, and if so whether there is sufficient evidence to generalize that conclusion.¹

But, as discussed below, there is insufficient evidence to demonstrate that FAW increases the probability of deep joint infection under either scenario. That was the conclusion of the recent CDC *Guideline for the Prevention of Surgical Site Infection, 2017* (1). Likewise, the nonprofit ECRI Institute recently concluded:

“Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods.” (5)

And in addition, the following statement is from a Continuing Education statement by the Association of periOperative Registered Nurses (AORN):

“Our review uncovered no conclusive evidence that the use of forced-air warmers increases the risk of SSIs”. (6)

12. Dr. Samet illustrated the use of that model in his Figure 2 (“Adaptation of Sufficient Component Cause Mode to Deep Joint Infection Risk”), which he described as a “hypothetical [that] shows how the presence of BH device increases risk”. Two aspects of this illustration should be noted:

12a. As proposed, his model addresses “how the presence of BH device increases risk”; but the relevant question is not how, but whether it increases risk and if so, to what extent. In other words, the model that he describes prejudices the central question: does use of BH result in increased rates of surgical infections?

12b. In Figure 2b, Dr. Samet presented and contrasted three alternative “Sufficient Component Causes” for development of post-operative deep joint infections. The first two Causes differ by the inclusion of “surgical procedure factors” in the second, but not the first. The second and third Causes differ in two ways: BH is a component of the third Cause but not the second; and “surgical procedure factors” is a component of the second Cause but not the third. That third Cause, which ignores “surgical procedure factors”, is the one that Dr. Samet proposed as showing “how the use of the BH device increases risk for disease” and on which his general causation opinion depends:

¹ Even if there were sufficient evidence to conclude a difference between two alternative warming methods, it would not necessarily indicate that the inferior method “caused” the adverse outcomes (i.e., SSI). Instead, it might be a question of the relative efficacies of two beneficial methods. For example, both BH and non-FAW might be beneficial, as suggested by the evidence that maintenance of body temperature during surgery reduces risks of SSI, but one might be more beneficial than the other. It is not obvious that in such a case “less efficacy” should be seen as equivalent to causation of the adverse effect. In that case, both methods could be seen as positively contributing to the public health, although one might be preferred.

“With regard to the question of general causation, evidence is considered as to whether evidence supports the existence of Cause 3 in Figure 2.”

It might be suggested that his ignoring of “surgical procedure factors” in Cause 3 of Figure 2 simply reflected limitations in Dr. Samet’s effort to illustrate his method. However, as discussed below, it is essentially the analytical approach that he actually adopted in his analysis of the McGovern study, which he characterized as “the one directly relevant observational study in the peer-reviewed literature”. His opinion on that critical report relied on only a univariate analysis of BH vs. a non-FAW device, while ignoring a variety of other relevant “surgical procedure factors”.

13. Dr. Samet also described his “framework for causal inference”, four elements of what are often referred to as the “Hill Criteria” (7): temporality; strength of association; consistency; and coherence. He proposed, and I agree, that concern about temporality is not an issue here because, by definition, use of warming devices during surgery precedes the development of post-operative SSI. Thus, his “framework” specifically includes the other three elements, which I will reference in my discussion below.

III. Validity

14. To be meaningful, an inference of causality necessarily assumes that the evidence and data supporting that inference are valid. Likewise, if the underlying facts are not valid, then it follows that inferences which rely on those facts would also not be valid. Accordingly, concerns about the validity of studies on which an inference is based are also concerns about the validity of that inference.

15. The validity of a study is usually described as comprised of two components, *internal validity* and *external validity*. The following description of those two components is from the third edition of a classic epidemiology textbook by Rothman et al (8):

“The validity of a study is usually separated into two components: the validity of the inferences drawn as they pertain to the member of the source population (*internal validity*) and the validity of the inferences as they pertain to people outside that population (*external validity*).” (p.129)

A similar description is found in the most recent edition of *Reference Manual on Scientific Evidence* (9).

“*Internal validity* is about the specifics of a particular study... *External validity* is about using a particular study or set of studies to reach more general conclusions. (p.222)

Likewise, the following description is taken from the 2016 edition of *A Dictionary of Epidemiology* (10):

“Internal Validity: The degree to which a study is free from bias or systematic error ... Internal validity depends on methods used to select the study subjects, collect the relevant information, and conduct analyses ... External Validity: The degree to which results of a study may apply, be generalized to, or be transported to populations or groups that did not participate in the study.” (p.287)

16. Internal validity is considered “a prerequisite for external validity” (8). Beyond their more immediate limitations, studies that lack internal validity do not have external validity and they cannot be generalized. Thus, evaluation of internal validity is a essential starting point for evaluating the adequacy of a study (or set of studies) proposed to serve as the basis for causal inference.

There is general agreement that a major issue in determining internal validity of studies, particularly observational studies, is the comparability of treatment and control groups. That view is expressed in the *Reference Manual* (9):

“Threats to internal validity include confounding and chance differences between treatment and control groups.” (p.222)

It is also found in Rothman et al. (8):

“Internal validity implies validity of inference for the source population of study subjects ... Most violations of internal validity can be classified into three general categories: confounding, selection bias, and information bias where the latter arises from mismeasurement of study variables.” (p.129)

It is likewise articulated in *Dictionary of Epidemiology* (10):

“Internal validity depends on methods used to select the study subjects, collect the relevant information, and conduct analyses. For instance, the index and comparison groups must be selected and compared in such a manner that the observed outcome differences between groups, apart from sampling error, be attributed only to the exposure of interest.” (p.287)

17. Accordingly, in evaluating the evidence that sustains Dr. Samet’s report, I will specifically focus on concerns of internal validity, particularly evidence of confounding.

Confounding

18. Confounding is said to occur when the association between exposure and effect is distorted by some third variable. It occurs when there is “a confusion of effects” (8):

“On the simplest level, confounding may be considered a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of extraneous factors is mistaken for – or mixed with – the actual

exposure effect (which may be null) ... confounding occurs only if extraneous effects become mixed with the effect under study.” (8)

In general, a *confounder* is a variable that is associated with both the exposure under study and the outcome of concern. In other words, it is both an independent risk factor for that outcome and associated with the exposure under study. For example, assume an operating room offers warming devices and prophylactic antibiotics to surgical patients: some patients receive both, some receive neither, and some receive only one or the other. If the device and the antibiotics were independently associated with risk of surgical infection, then the risk of infection due to the device might be confounded by use of the antibiotic.

19. Confounding can impact any type of study, but it is of particular importance to observational studies, which by their nature are unable to fully control for many possible differences between exposed and control subjects. That concern was described in *Reference Manual* (9):

“In a controlled experiment, the investigators decide which subjects will be exposed and which subjects will go into the control group. In observational studies, by contrast, the subjects themselves choose their exposures. Because of self-selection, the treatment and control groups are likely to differ with respect to influential factors other than the one of primary interest. (These other factors are called lurking variables or confounding variables.) ... Confounding remains a problem to reckon with, even for the best observational research.” (p.219)

To achieve validity in such studies, efforts should be made to minimize possible differences in the composition and treatment of the groups, other than that which is the subject of the study. For example:

“Proper evaluation of the association between a particular exposure and a certain disease pre-supposes that every other factor which could influence disease occurrence is either constant or distributed in a balanced way between exposed and unexposed subjects.” (11)

20. While it may not be possible to avoid all such problems when undertaking an observational study, it is usually possible to analyze the study, recognize the inherent problems, and then, in many cases, adjust the analysis to address the effects caused by problems such as confounding. That approach was espoused by a large group of prominent epidemiologists, including Dr. Samet, in a recently published commentary:

“It is well known that observational epidemiologic studies may be affected by various biases that can impair their validity, and that are generally not present in experimental investigations. A strength of epidemiology is that it is based on real world conditions. Critical scrutiny of epidemiologic studies, covering all potential sources and mechanisms of biases, is indispensable.” (12)

“Epidemiologists are well aware of the potential for confounding to introduce noncausal association and generally take steps in the design and analysis phases of research to address confounding.” (12)

The same thoughtful approach was advocated by Rothman and Greenland in an article that was repeatedly cited in Dr. Samet’s expert report:

“Although there are no absolute criteria for assessing the validity of scientific evidence, it is still possible to assess the validity of a study. What is required is much more than the application of a list of criteria. Instead, one must apply thorough criticism, with the goal of obtaining a quantified evaluation of the total error that afflicts the study. This type of assessment is not one that can be done easily by someone who lacks the skills and training of a scientist familiar with the subject matter and the scientific methods that were employed. Neither can it be applied readily by judges in court, nor by scientists who either lack the requisite knowledge or who do not take the time to penetrate the work.” (13)

Likewise, note the following statement from the 2004 *Report on the Health Consequences of Smoking: A Report of the Surgeon General*, for which Dr. Samet was the Senior Scientific Editor:

“If confounders are recognized and their effects measured, these effects can often be statistically minimized or removed by the analysis of a study. However, if a confounder is poorly measured, or its effects poorly characterized, then its effects cannot be controlled for in the analysis phase of a study, resulting in a causal effect that is distorted or confounded by the unwanted factor. The most extreme version of this phenomenon occurs with unmeasured confounding, causal factors that are not measured at all and whose effects are therefore not controllable, which can result in biased estimates and underestimates of uncertainty, because standard analyses implicitly assume an absence of confounding from all unmeasured factors.” (14)

21. However, in his expert report, Dr. Samet was seemingly dismissive of concerns about confounding, and he apparently did not engage in a critical analysis of the potential sources of confounding and bias as he advocated in his published work. With respect to the McGovern study and suggestions that its results potentially reflected confounding, he rejected such suggestions as merely reflecting the partisan views of those who would obstruct public health initiatives:

“This finding has been criticized as potentially reflecting confounding ... These arguments are the typical general claims made by those seeking alternative explanations for an association, and reach back to the strategies employed for decades by the tobacco industry”.

His analogy seems misplaced and excessive. It is all but certain that, from a public health perspective, the potential adverse effects associated with the choice of warming

devices do not rise to the level and magnitude of those associated with smoking.² In addition, his approach is contrary to that advocated in his writing and in the writing of others whom he apparently respects. Finally, in his actual analysis of the McGovern study, he ignored a number of potentially critical confounders. These concerns are discussed below.

The McGovern Study: Background

22. The report by McGovern et al. (15) is the only published study that purports to show an increased risk of SSI associated with the use of BH. It is the study that Dr. Samet described as the “one directly relevant observational study in the peer-reviewed literature”. The published report described rates of deep-joint infection in patients who underwent “planned” primary hip and knee replacement procedures; trauma patients were excluded [Reed deposition, p. 61-62]. The procedures were performed at the Wansbeck Hospital, a component of Northumbria Healthcare Trust [Reed depo, p. 29; Albrecht depo p.144]. The report included a total of 558 hip cases and 879 knee cases performed over 27 months: 7/01/08-2/28/08, and 6/01/10-12/31/10.

23. Rates of infections documented within 60 days of surgery were reported and compared for the 20 months (7/08 thru 2/10) when the BH device was used exclusively and the 7 months (6/10 thru 12/10) when a non-FAW device was used exclusively. Results from a 3-month transition period were excluded. The data were analyzed using a univariate logistic regression that found a significantly increased odds ratio (OR) for SSI during the BH period (OR = 3.8, p=0.024). SSI were more frequent after hip than knee replacement surgeries (4.5% vs. 1.1 %).

24. The McGovern authors noted that “unfortunately” during the study period there was a change in their prophylactic antibiotic regimen and two changes in their thromboprophylaxis regimen. They did not include those two changes among the risk factors in their analyses. They also noted the “somewhat unusual” finding that risk of SSI was more than four-fold greater after hip than knee replacement, although “typically, infection risks are greater for knee replacement” (15). The increased risk after hip surgery was not affected by type of warming device.

25. The authors concluded that their study did not establish a causal basis for an association between BH and risk of SSI, largely because of various potential confounders, particularly involving infection control measures:

“This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital.” (15)

² Beyond the sheer magnitude of the adverse public health effects of smoking, the association of health risks with tobacco was consistently found in dozens and dozens of studies, nearly forty at the time of the original Surgeon General’s report, whereas in the present case Dr. Samet can cite only one observational study proposing a link between BH with SSI.

That concern was echoed in their deposition. For example, Mr. Albrecht:

A. ... This study simply looked at trends over time and infection rates. And the reduction in infection rates shown in the study could be due to the adoption of conductive fabric warming or it could be due to other outside factors.

Q. What other outside factors could have influenced it?

A. Well, it could be anything. Improvement in surgical practices, perhaps. There's an antibiotic switch that was occurring somewhere in the study's period. You could have a different group of physicians operating. These are all uncontrolled things that don't get caught with observational research.

[Albrecht depo p. 134]

"This is an observational study. These things aren't controlled for. You can't make a causal inference, and we did not. The study does not establish a causal basis and that's -- there's a lot of compounding factors that could be at play."³

[Albrecht depo p. 178]

"... I see other confounding factors that might be at play. I don't know. It's uncertain, like a lot of these things."

[Albrecht depo p. 204]

Likewise, the deposition of Dr. McGovern:

A. It's important to mention confounding factors, which is part of the whole purpose of not attempting to imply that this is causation ... Confounding factors such as different types of thromboembolic prophylaxis, different antibiotic prophylaxis regimens, and any other measures that may be taken...

...

Q. And if I understood what you just said, you wanted to avoid even implying that there was a causal connection?

A. I don't remember the precise words I used. What I mean to say is that I would not want to make a claim which was not reasonable in a paper, and based on the evidence that we had, I would not want to claim that there was a causation, or that we that proved or demonstrated a causation

...

A. ... we recognize there are confounding factors ...there are other effects that could be at play.

[McGovern depo p. 113-5]

Dr. Reed also testified as follows:

Q.... What does it mean that there is -- that the study does not establish a causal basis?

...

³ I believe that this statement contains a transcription typo: the phrase "compounding factors" should have been "confounding factors", as was correctly transcribed in the following quote from that transcript.

A. So what we have shown is association and not causation. We made that pretty clear in the paper. [Reed depo p. 229]

26. As noted, the McGovern authors were concerned about the possible effects of confounding, particularly those due to changes in antibiotic and thromboprophylaxis regimens. They also referred to “other confounding factors that might be at play”, but provided no details. However, review of the published McGovern report as well as other contemporaneous and historical reports, deposition testimony, and the expert reports of Drs. Holford and Wenzel indicate a variety of confounding factors and sources of bias that potentially impacted this study in addition to the two identified in McGovern.

The McGovern Study: Sources of Confounding and Systematic Bias

27. The McGovern study focused on a time when there was a concerted effort at Wansbeck Hospital to reduce surgical infection rates because surgical infections were seemingly out-of-control. As described by Gillson and Lowdon (16), the Northumbria Healthcare Trust was regularly informed by the Health Protection Agency during 2008 and 2009 that it was “a high outlier for SSI”. This was confirmed by Dr. Reed in his deposition [Reed depo p.66]. The magnitude of that excess can be appreciated by comparing the SSI rates after primary hip and knee replacement reported by McGovern to the corresponding rates for all National Health Service (NHS) hospitals in England. As reported by the NHS, between 2008 and 2011 the annual cumulative rate of SSI after primary knee replacement was less than 0.6%, and less than 0.7% after primary hip replacements (see Figures 2b and 2d in (17)). Thus, the Northumbria rates were 2- to 6-fold higher than corresponding national rates.

28. Another perspective on the SSI problem at Wansbeck Hospital is seen in an analysis of infection time trends conducted by Dr. Holford using the dataset [Albrecht depo exhibit 10] that underlies the McGovern report. As described in his report, the occurrence rates of SSI was “highly variable”, with two peaks, one in late 2008 and a second more dramatic peak in late 2009-early 2010, suggesting outbreaks of infection. During the latter peak, rates were nearly 14-fold higher than the NHS average. By contrast, the lowest SSI rates were seen in late 2007 and early 2008, a time period when BH was used, but that was not included in the McGovern study.

The erratic and variable pattern of SSIs and the fact that the lowest rate of infection occurred during a nearly 9-month period when BH was used suggests that the infections reported in the McGovern study reflected infection control problems, not use of BH. The “somewhat unusual” finding that infection risks were more than four-fold greater after hip than knee replacement also suggests that infection control problems may have been unique to specific surgeons or specific surgical procedures.

29. The analysis by Dr. Holford raises another concern, the possibility that the data included in the McGovern study had been “cherry-picked”. As noted above, appropriate SSI data were available for the 9 months from 10/07 to 6/08, but they were excluded from the McGovern report. Dr. Holford demonstrated that the statistically significant

difference in SSI rates between BH and non-FAW devices in the McGovern study depended on the study start date. If the McGovern authors had included one or more of the excluded months, their results would not have been significant. It is possible that exclusion of those data was unintended, but it suggests the possibility of data manipulation. And, regardless of motive, it raises important questions about the meaningfulness and generalizability of the McGovern study findings.

30. As described by Gillson and Lowdon and also by Dr. Reed in a published report (18), numerous interventions were introduced to reduce the SSI rates. Figure 2 in Gillson and Lowdon describes the “Trust Wide Surgical Site Infection Intervention Timeline for Orthopaedic THR & TKR Surgery”. See also the related discussion of exhibit 5 in Dr. Reed’s deposition. The list of interventions was long, but I will discuss a number of them below in more detail. This concerted effort (“The SSI Bundle”) was successful: SSI rates at Northumbria Healthcare after hip and knee replacement and repair of the neck of femur declined from 5% to 0.9% (16).

31. Because so many changes were made in surgical process and procedures, it is difficult to ascribe the effort’s success to any one of them individually. More notably, because SSI rates declined markedly over time, any procedure specific for the earlier time period would have appeared to be associated with higher SSI risks, while an alternative employed only during the later period would have appeared to be associated with lower risks. However, it would not be simple to conclude that such procedural changes led to the decline in rates. Given a background of steeply declining rates, it is likely that any change, even one with no actual effect, would have appeared to be beneficial. Likewise, any procedure utilized only at the beginning of the time trend would appear to have contributed to SSI. The presence of such an unequal baseline is an example of systematic bias.

The McGovern Study: Prophylactic Antibiotics

32. There were several process changes that occurred during the McGovern study time period. The authors specifically noted changes in prophylactic antibiotic regimens, but they were not included in the study analysis. Prior to 3/09, patients received a single dose of gentamicin (4.5 mg/kg). After 3/09 they received gentamicin (3 mg/kg) plus teicoplanin 400 mg. Thus, gentamicin was administered alone just during the first half of the BH time period. If use of gentamicin alone was less effective against SSI, then that could have caused BH to be associated with higher infection rates. In that case, the antibiotic regimen would be a confounder.

33. The most common bacteria causing SSI after hip and knee replacement surgery are *Staphylococcus aureus* and coagulase-negative *Staphylococcus*, which are reported to cause 50-60% of prosthetic joint infections (19;20). An English study coauthored by Dr. Reed reported that during 2010-2013, *Staphylococcus* species represented 54.9% of SSI after hip and knee replacement (20) and a CDC study during 2006-09 found that *Staphylococcus* comprised 63% of SSI following arthroplasty (21).

34. *Staphylococcal* species have increasingly developed resistance to a spectrum of antibiotics, including gentamicin. A survey of *Staphylococcus* isolates from 19 European hospitals found that overall, 23% were gentamicin-resistant including 33% of coagulase-negative *Staphylococcus* (22). Similar data have been reported worldwide, including epidemics in individual hospitals (23;24). In discussing gentamicin resistance at the Northumbria hospitals, Dr. Reed reported that “our infection rate doubled when we went to Gentamicin” (18) and that following introduction of prophylactic gentamicin, the rate of return to theater because of SSI increased significantly, from 0.66% to 1.52% ($p < 0.01$): “We recommend that single dose Gentamicin (4.5 mg/kg) alone is not used as prophylaxis for joint replacement” (25). A recent NHS report found that none of the National Trust hospitals used gentamicin alone as a prophylactic for joint replacement surgery, while 84% use teicoplanin alone or in combination with gentamicin (17).

35. Gentamicin was used alone only during the BH time period. There is evidence that *Staphylococcal* species are often resistant to gentamicin. Such resistance to gentamicin has been reported to be about 10-fold more common than resistance to teicoplanin (26). Accordingly, it is reasonable to suggest that use of gentamicin alone during the BH time period led to higher rates of SSI than were seen during the non-FAW device period, when gentamicin and teicoplanin were both used. In that case, the comparison between warming devices was confounded by the prophylactic antibiotic regimen.

The McGovern Study: MSSA Screening

36. Another procedural change during the McGovern study period was the adoption in January, 2010 of nasal screening for methicillin-sensitive *Staphylococcus aureus* (MSSA). The purpose of this intervention was to reduce the rate of SSI in the subgroup of patients who are nasal carriers of the bacteria (27;28). It is estimated that 20% (range 12-30%) of the population are persistent nasal carriers of *S aureus*, about 30% (range 16-70%) are intermittent carriers, and about 50% are non-carriers (28).

37. Nasal carriers of *Staphylococcus* have significantly higher risks of SSI than do non-carriers (29). More importantly, decolonization with a topical antibiotic, mupirocin, has been shown to significantly reduce risk of post-surgical infections including hip and knee replacement procedures (20;30;31). It is estimated that nasal screening followed by use of mupirocin reduces *Staphylococcus aureus* SSI by about 50% (30;31). In a recently published article, Dr. Reed and colleagues recommended adoption of such screening and decolonization of nasal carriers prior to joint replacement surgery (32):

“Carriage is common ($\approx 20\%$) and decolonization presents us with an easy ‘high yield’ strategy in the fight against PJI [prosthetic joint infection] ... After MSSA screening and decolonization was introduced in one NHS joint replacement unit, the MSSA infections reduced from 0.84% to 0.26% ...”

Note that his comment about the success of this approach at “one NHS joint replacement unit” specifically referenced infection rates at Northumbria Healthcare.

38. MSSA screening was performed during the last two months of the BH time period, and the entire non-FAW time period. To the extent that it reduced SSI, it would have been almost entirely during the non-FAW period. Accordingly, it is reasonable to suggest that implementation of MSSA screening would have disproportionately reduced the rate of SSI in the non-FAW cases, thereby wrongly suggesting a benefit attributable to the non-FAW device. In that case, the comparison between warming devices was confounded by the adoption of MSSA screening.

The McGovern Study: Skin Preparation

39. Another intervention that changed during the McGovern study period was the method of surgical-site skin preparation. Use of chlorhexidine-alcohol for skin preparation began in October, 2010 (16). Before that, skin preparation was performed using povidone-iodine. Speaking of his adoption of chlorhexidine in place of povidone, Dr. Reed opined: “If your surgeon is still using iodine plus alcohol then there is a very robust study that shows that they could do better” (18). Use of chlorhexidine - alcohol has been reported to reduce SSI by up to 40% compared to povidone-iodine (33) and it reduced infections related to vascular catheters by 49% (34). CDC found that “high-quality evidence suggested a benefit of CHG-alcohol [chlorhexidine gluconate-alcohol] as compared with aqueous iodophor” (1). There is also evidence that the combination of MSSA screening and chlorhexidine was complementary, resulting in a five-fold reduction in deep SSI compared to the placebo (35).

40. Use of chlorhexidine for skin preparation began in October, 2010. Thus, it was used only during the last three months of the non-FAW time period. During that time, it was used in conjunction with MSSA screening. To the extent that use of chlorhexidine reduced SSI, it would have only reduced the rate of SSI in non-FAW cases, thereby wrongly suggesting a benefit attributable to the non-FAW device. In that case, the comparison between warming devices was confounded by the adoption of chlorhexidine skin preparation.

The McGovern Study: Antithrombotic Prophylaxis

41. The antithrombotic prophylaxis regimen was changed twice during the McGovern time period. Initially, patients were treated with Tinzaparin (a low molecular weight heparin). Between August, 2009 and February, 2010, that medication was replaced by Rivaroxaban (an oral anticoagulant). Then, in March 2010, Tinzaparin was reinstituted in place of Rivaroxaban. Accordingly, Rivaroxaban was administered to BH cases during those seven months; it was not administered to any non-FAW cases. According to a published report that quoted Dr. Reed, the change to Rivaroxaban was problematic: “We changed to Rivaroxaban from Tinzaparin and found that returns to theatres from wound complications more than doubled” (18). These medication changes were noted in the McGovern paper, but they were not included in the study analyses.

42. A second retrospective study was conducted at Wansbeck Hospital to evaluate the potential adverse effects of antithrombotic prophylaxis in hip and knee replacement patients. That study, the Jensen study (36), included Dr. Reed as an author. It included 489 cases treated with Rivaroxaban during six months (2/09-7/09), and 559 cases treated with Tinzaparin during seven months (8/09-2/10). The authors reported that the Rivaroxaban patients had an increased rate of deep joint infections (2.5% vs 1%), but the difference was not statistically significant. This study was cited by Dr. Samet in his report as evidence of a lack of confounding by antithrombotic medications in the McGovern study.

43. However, significant differences between the Jensen and McGovern studies invalidate that conclusion. For example, given that those two studies overlapped in time and place, and both included only patients who had undergone hip or knee replacement, one would expect that each would have reported the same number of cases for that 13-month time period. But that is not so; Jensen et al. reported significantly more cases.

44. To understand these differences, Dr. Holford reanalyzed the McGovern dataset [Albrecht depo exhibit 10] for the 13 months considered by Jensen, but applying the methodological criteria used by McGovern. For example, McGovern considered infections that developed within 60 days of surgery, while Jensen considered a 30-day window. In addition, McGovern excluded trauma patients (generally reported to have higher rates of SSI), but Jensen did not. When the McGovern approach is taken, the analysis finds that the Tinzaparin SSI rate was 0.98% and the Rivaroxaban rate was 4.5%, a statistically significant difference. In other words, analysis of the data in a manner comparable to the McGovern approach found that the antithrombotic regimen was a highly statistically significant confounder (with an odds ratio higher than that presented in the McGovern paper) that would have wrongly suggested a benefit attributable to the non-FAW device.

45. In his expert report, Dr. Samet also cited a second study, the Jameson study (37), as evidence that antithrombotic medications did not confound the infection rates reported in the McGovern study. However, the data provided in Jameson do not inform that question. Table II of that study indicates that there was no difference between the two antithrombotic medications with respect to “return to surgery for infection”, which seemingly supports Dr. Samet’s view. But, the text states that the Jameson authors, whose study pooled data from numerous hospitals, could not distinguish between cases that returned to surgery for surgical irrigation for infection and those that returned for surgical treatment of hematoma, and that the authors simply combined infections and hematomas:

“The primary outcome measure was wound complications (including hematoma, superficial wound infection, and deep infection requiring return to surgery) within thirty days of the procedure ... It was not possible to discriminate between repeat surgical wound irrigation for infection and surgery for hematoma. However, as there is substantial overlap in the treatment and immediate health care

requirements of these conditions, it was felt that the combined data were adequate for the needs of this study.” (37)

Moreover, the data provided in Table II are apparently incorrect.

45a. For the group of cases that received low molecular weight heparin (e.g., Tinzaparin), the Table indicates 291 “total wound complications”, 243 of which were “managed nonoperatively” and 55 that were “return to surgery for infection”. If those numbers were correct, then there would have been at least 298 complications ($243 + 55 = 298$), not 291. Moreover, the Table seemingly ignores cases requiring surgery because of hematoma.

45b. For the group of cases that received Rivaroxaban, the Table indicates 106 “total wound complications”, 97 of which were “managed nonoperatively” and 17 that were “return to surgery for infection”. If those numbers were correct, then there would have been at least 114 complications ($97 + 17 = 114$), not 106. And as above, the Table seemingly ignores cases requiring surgery because of hematoma.

Accordingly, it is my opinion that the Jameson report presents inconsistent data that cannot inform concerns about the potential for antithrombotic medications to confound the apparent infection rates associated with warming devices.

46. To determine the impact of the antithrombotic regimen on infection rates, Dr. Holford reanalyzed the McGovern data after controlling for its effects by comparing only BH and non-FAW device while Tinzaparin was administered. As described in his report, that analysis found no statistically significant difference between BH and non-FAW. He also performed a reanalysis that controlled for both antithrombotic and prophylactic antibiotic regimens. He compared BH and non-FAW device while both groups were medicated with Tinzaparin and Teicoplanin plus gentamicin. In that reanalysis, the infection rates in the two groups were nearly identical.

These analyses demonstrate the importance of confounding by antithrombotic regimen and prophylactic regimen.

The McGovern Study: Hawthorne Effect

47. The “Hawthorne Effect” describes a psychological phenomenon in which subjects under observation, often in a research context, modify their behavior as a consequence of being under observation. The term originated from studies conducted at Western Electric’s Hawthorne plant where the effects on worker productivity of a variety of job and environmental modifications were assessed. In the original studies, productivity rose under both “positive” and “negative” conditions, which was interpreted as a result of the workers being observed and of receiving explicit feedback on their performances (38). Similar effects have been described in health care workers, who tend to comply more readily with hygiene procedures, such as use of antiseptic hand wipes, when they

are aware of being observed and when there is ongoing encouragement (39). The Hawthorne Effect is seen as a confounder of research studies because changes in performance are due to the fact that the subjects are in a study and under observation, not necessarily because of the variables that are being studied (38).

48. Consider the concerted efforts undertaken to reduce SSI at Wansbeck Hospital. The following description of that effort is from a proclamation that accompanied an award given to Northumbria Healthcare for successfully reducing its SSI rates in orthopedic surgery (40):

“Program Overview: Transforming the culture and behavior of a 200-strong, multi-disciplinary team is at the heart of Northumbria’s successful campaign to reduce infection rates in orthopaedic surgery.

The Solutions: ... The improvements in theatres included ... further raising awareness among staff of the importance of infection control. Communicating the policy objectives and the progress of the improvements were key to the programme’s success ... updates were given regularly to a number of different groups and committees ...”

Such efforts, over and beyond the choice of antibiotics, antithrombotics, skin cleansing products and warming devices, would have contributed to the reported improvements in SSI. Their impact on staff behavior would have contributed to declining rates of SSI over time, thereby wrongly suggesting a benefit attributable to the non-FAW device. In that case, the comparison between warming devices would have been confounded by something akin to the Hawthorne Effect that resulted from ongoing efforts to “transform the culture and behavior of a 200 strong multi-disciplinary team”.

The McGovern Study: Data Irregularities

49. In an earlier paragraph, I noted the possibility that the McGovern study data had been “cherry picked” by selecting a starting date to ensure that the SSI rate difference between BH and non-FAW would reach statistical significance. There is also a second data irregularity, an apparent tabulation error. McGovern et al. described SSI in 32 of 1066 BH cases and 3 of 371 non-FAW cases, but there is reason to believe that one of the 32 BH infections should have been tabulated as a non-FAW infection.

50. The tabulation error can be seen by examination of the Wansbeck Hospital infection data for arthroscopic surgery, a spreadsheet that was marked as McGovern Exhibit 16. This spreadsheet, which was discussed during Dr. McGovern’s second deposition, contains data on 46 surgical patients, including five treated prior to July, 2008 who were not included in the McGovern study, six treated during the three-month transition period who also were not included in the study, and 35 cases that were included in the study. The apparent error concerns patient 44, who underwent hip replacement surgery on September 15, 2010 and was then diagnosed with a *Staphylococcal* SSI on October 3, 2010. Given the dates of the patient’s surgery and

diagnosis, s/he should have been included in the non-FAW group. However, column BR of the spreadsheet indicates that the patient was included instead in the BH group.

51. The fact that the data presented in the McGovern paper were not all correct was conceded by Dr. Reed in his deposition testimony:

“It’s clear to me that some of the data on the clinical side are wrong” [Reed depo p. 43].

He further testified that he had brought this to the attention of Mr. Albrecht, but it was not corrected in the final paper.

Likewise, Mr. Albrecht testified that there were conflicts between the dataset used in the published McGovern paper and an updated data file that he had also analyzed:

“And it looks like it didn’t line up a hundred percent, so I ran the analysis, I’m not sure what’s going on...” [Albrecht depo p.163]

He also agreed that he had sent an email to Dr. Reed concerning those data conflicts and cautioned him not to distribute the new results:

“I’ve done a quick analysis of the new data and the trend does persist, but the data files are not totally consistent (in regards to the data the brJBJS article was based upon) ... In fact, in the data file you sent me the infection rate during the forced air warming period was slightly lower than the previous one ... I’m giving you a graphic for the Wansbeck data, but do not distribute for it ‘slightly’ conflicts with the study data ...” [Albrecht depo exhibit 12]

It seems that the McGovern authors understood that their published report contained incorrect data, but they did not correct the data and they did not subsequently publish an *erratum* or letter to the editor.

52. It is important to consider whether this tabulation error affected interpretation of the study. As described in his expert report, Dr. Holford performed such an analysis. He compared two alternatives, the data as published in McGovern (with patient case 44 in the BH group) and the corresponding data from McGovern Exhibit 16 with patient 44 included in the non-FAW group.

52a. In the first analysis, infection rates were BH: 3% and non-FAW: 0.8%. The OR was 3.79, the 95% confidence interval was 1.15-12.45, and p-value using Fisher’s exact test was 0.0176. Thus, the analysis demonstrated a difference that was statistically significant.

52b. In the second analysis, infection rates were BH: 2.91% and non-FAW: 1.08%. The OR was 2.76, the 95% confidence interval was 0.97-10.82, and p-value using Fisher’s exact test was 0.0507. Thus, in contrast to the previous

example, this analysis demonstrated a difference that was not statistically significant, as reflected by both p-value and confidence interval.

Thus that the tabulation error importantly impacted the interpretation of the study.

53. In summary, the reported conclusions of the McGovern study depend at least in part on two data irregularities. If the study had not excluded the eligible SSI data from 10/07 to 6/08, then the study would have had no significant clinical findings. Likewise, if the tabulation error described above had been corrected, then the study would have had no significant clinical findings.

The McGovern Study: Summary

54. The McGovern study, the “only directly relevant observational study” and also apparently the only study that has reported a significant SSI increase associated with BH, is fundamentally flawed. It has an inherently weak study design and it is plagued by bias, confounding, and data irregularities.

55. The study was performed during a time when infections were seemingly out-of-control. The monthly infection rates showed great variability and peaks, suggesting that whatever contributed to infection risks was inconsistent and not systematic.

56. There were numerous potential sources of confounding that were not directly considered and the authors used a univariate analysis, which failed to consider the impact of any of those factors on the infection rates attributed to the warming devices. Exhibit C, attached to this report, indicates the timelines of the McGovern study and the various Wansbeck OR procedures discussed above as potential confounders.

57. The data in the published study were incorrect, which the authors admitted but did not correct, and there is reason to suggest that the data may have been manipulated. In either event, reanalysis of the corrected data using appropriate tests indicates that the study findings were not statistically significant.

58. The authors agreed that the meaningfulness and generalizability of the study were limited because of such concerns. Thus, Mr. Albrecht testified that the study “does not establish a causal basis” [Albrecht depo p. 176] and Dr. McGovern testified: “I would not want to claim that there was a causation, or that we that proved or demonstrated a causation” [McGovern depo p. 114].

59. Accordingly, it is my opinion that the McGovern study lacks internal validity, and therefore it lacks external validity. Its results cannot be generalized.

The Samet Opinion

60. Dr. Samet concluded that “the Bair Hugger device causally increases risk for deep joint infection” based on review of the strength of association, consistency and coherence of the literature that he reviewed. I will consider those criteria separately.

61. With regard to Strength of Association, Dr. Samet referenced only the McGovern study, which he described as “a statistically significant association unlikely to be explained by confounding or other bias. The relative risk is estimated at 3.8”. But as discussed above, the study is plagued by numerous sources of bias and confounding that were not incorporated into the analysis. Those sources of bias and confounding each tended to either increase the apparent risks of BH or decrease the apparent risks of non-FAW devices. McGovern was the only study that Dr. Samet identified that purports to show an increased risk of SSI associated with use of BH.

62. In addition, the analytical results published in McGovern and cited by Dr. Samet were based on incorrect data. When corrected, the study does not yield statistically significant results and the estimated relative risk (actually the OR) is not 3.8. Also, the first nine months of eligible data were excluded. If the data series had not been truncated, the difference in infection rates would have been even smaller (OR: 2.1, 95% confidence interval 0.75-6.0) and further from significance ($p=0.2179$). Thus, the apparent “strength” of this study depends on the inclusion of incorrect data and the exclusion of eligible data.

63. In discussing strength of association between BH and SSI, Dr. Samet also referred to “the studies summarized in Table 3” that considered “various tracers over the surgical site”. However, none reported increased rates of SSI and therefore none contributed to the strength of association between use of BH and SSI. To the extent that they are relevant to his opinion about BH and SSI, I will consider them below in the context of *coherence*.

64. In short, it is my opinion that the McGovern study does not provide support for a finding of *strength of association* between BH and SSI. It is also my opinion that given the faults of the McGovern study and the apparent lack of other supporting evidence, there is no direct evidence that BH increases risks of infections in orthopedic surgical patients.

65. Dr. Samet next discussed Consistency, which he said “is generally applied to findings from multiple observational studies”. The following is from Hill’s classical description of consistency (7):

“Consistency: Next on my list of features to be specially considered I would place the consistency of the observed association. Has it been repeatedly observed by different persons, in different places, circumstances and times?”

Hill went on to exemplify consistency by reference to studies on smoking:

“Returning to my more general example, the Advisory Committee to the Surgeon-General of the US Public Health Service found the association of smoking with cancer of the lung in 29 retrospective and 7 prospective inquiries. The lesson here is that broadly the same answer has been reached in quite a wide variety of situations and techniques. In other words we can justifiably infer that the association is not due to some constant error or fallacy that permeates every inquiry. And we have indeed to be on our guard against that.”

Because consistency “is generally applied to findings from multiple observational studies”, and because the McGovern study was the “one directly relevant observational study”, Dr. Samet agreed that consistency is “not applicable” to that study.

66. On the other hand, it is meaningful to consider the lack of internal consistency in the McGovern data. As discussed above and illustrated in Dr. Holford’s Figure 2, the SSI rate was very inconsistent. During two time periods when BH was used, SSI rates were very low: the first nine months (that were excluded from the McGovern analysis) and the six months from 3/09 thru 8/09. At other times when BH was used, the rates were much higher, increasing nearly 16-fold at the end of 2009. Such variability suggests two discrete infection outbreaks, which were almost certainly not due to use of BH. Thus, it is clear that the data underlying McGovern are internally inconsistent.

67. The McGovern study is also inconsistent with the reported results of other studies that found no association between BH and SSI. Dr. Samet listed five such studies, which he described as “construed as ‘negative’ and indicating safety of forced-air warming”, but which he faulted for being “seriously constrained by limited size”. Without regard to the merits of those studies and their capacity to conclude a negative result, it is notable that none of them or any other of the studies cited by Dr. Samet provided evidence that BH is associated with increased rates of surgical infections. With the exception of the flawed McGovern study, there is no direct evidence that use of BH results in increased risks of infections in surgical patients.

68. Dr. Samet proposed, on the other hand, that consistency could be sought between the McGovern study and studies “on particle counts”. I assume that he was referring to the first half of McGovern, an evaluation of “neutral-buoyancy detergent bubbles” which might be analogous in behavior to airborne dust particles, but not the second half of that study which reported surgical infection data. There might be consistency among the bubble/particle studies. But it is not meaningful to apply the concept of consistency as defined above to the particle studies and the clinical half of the McGovern study, because they share no “observed association” for which consistency could be sought. Particle deposition patterns are not equivalent to surgical infection rates.

69. In short, it is my opinion that the data underlying the second half of the McGovern study, the surgical infection data, were internally inconsistent. It is also my opinion that it is not meaningful to look for consistency between reports of clinical findings and the

studies “on particle counts”. However, as discussed below, the particle count studies might contribute to coherence.

70. Finally, Dr. Samet discussed Coherence as it applied to studies that addressed hypothetical possible mechanisms by which BH might increase the risks of joint infection. The following is from Hill’s classical description of coherence (7):

“Coherence: On the other hand the cause-and effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease - in the expression of the Advisory Committee to the Surgeon-General it should have coherence.”

71. Dr. Samet apparently meant that those mechanistic studies were coherent with an increased risk of deep joint infections in BH users, as described in McGovern. But as already discussed, the McGovern study does not correctly demonstrate a significantly increased risk of such infections, and I am not aware of any other evidence that documents such increased risk. Therefore, there is apparently no proven disease with which the mechanistic studies can be coherent. In the absence of valid evidence of a causal association between BH and SSI, it can only be said that the mechanistic studies are coherent with a hypothetical increase in SSI. Hypothetical associations are not sufficient to sustain an inference of causation.

72. For the reasons listed above, it is my opinion that there is only insufficient evidence to support Dr. Samet’s conclusion that “the Bair Hugger device causally increases risk for deep joint infection”. A potentially causal association between BH and deep joint infections remains hypothetical and unproven.

73. Likewise, lacking sufficient and valid evidence that there is a significant causal association between BH and SSI, it is my opinion that BH does not represent a substantial contributing cause of deep joint infections.

Summary

74. Following is a list of my opinions, all to a reasonable degree of medical and scientific certainty.

74a. The McGovern report is flawed by systematic bias and confounders that were ignored in the analysis. In addition, the surgical infection data presented in that report were internally inconsistent.

74b. Accordingly, the McGovern study lacks internal validity. Because it lacks internal validity, the McGovern study also lacks external validity and cannot be generalized.

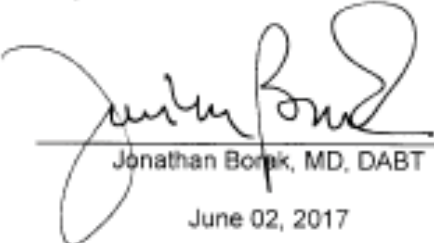
74c. The McGovern report relied on truncated and incorrectly tabulated data. When those irregularities are corrected, the study data do not provide evidence that BH is associated with a significant increase in SSI.

74d. Accordingly, the McGovern study cannot sustain Dr. Samet's opinion that "the Bair Hugger device causally increases risk for deep joint infection".

74e. There are no studies other than McGovern that show increased SSI associated with BH, and the McGovern study lacks validity and is based on incorrect data. Therefore, a causal association between BH and deep joint infections remains hypothetical and unproven.

74f. Because there is insufficient evidence that there is a significant association between BH and deep joint infections, BH does not represent a substantial contributing cause of deep joint infections.

75. I reserve the right to amend my report and opinions should further information become available.



Jonathan Borak, MD, DABT
June 02, 2017

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BORAK, Jonathan Benjamin

Page 1 of 26

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EDUCATION:

1968	BA (Cum Laude)	Amherst College
1972	MD	New York University
1974-76	Graduate Studies in Economics	McGill University

PROFESSIONAL TRAINING:

1972-73	Internship, Department of Medicine, Royal Victoria Hospital, Montreal, Quebec
1973-74	Junior Assistant Resident, Department of Medicine, Royal Victoria Hospital, Montreal, Quebec
1974-75	Clinical and Research Fellow, Department of Medicine, Royal Victoria Hospital, Montreal, Quebec
1975-76	Senior Assistant Resident, Department of Medicine, Royal Victoria Hospital, Montreal, Quebec
1976-77	Resident, Department of Medicine, Royal Victoria Hospital, Montreal, Quebec
1977-78	Clinical Fellow, Section of Gastroenterology, Yale-New Haven Hospital, New Haven, Connecticut

BORAK, Jonathan Benjamin

Page 2 of 26

COMPETITIVE FELLOWSHIPS, AWARDS and HONORS:

- | | |
|---------|---|
| 1974-76 | Clinical Scholar, Robert Wood Johnson Foundation. |
| 1977-78 | Research Fellowship, Conseil de la Recherche en Sante du Quebec |
| 1994 | President's Award, American College of Occupational and Environmental Medicine |
| 1996 | Meritorious Service Award, American College of Occupational and Environmental Medicine |
| 2002 | President's Award, American College of Occupational and Environmental Medicine |
| 2003 | Adolph G. Kammer Merit in Authorship Award, American College of Occupational and Environmental Medicine

"To recognize the author(s) of the most outstanding article published in <i>Journal of Occupational and Environmental Medicine</i> during the past year." |
| 2004 | Robert A. Kehoe Award of Merit Recognition, American College of Occupational and Environmental Medicine

"Presented to an individual for significant contributions made to academic excellence or research in the disciplines of occupational medicine, environmental medicine, and/or environmental health." |
| 2005 | George H. Gerchman Memorial Prize, American College of Occupational and Environmental Medicine |
| 2008 | President's Award, American College of Occupational and Environmental Medicine |
| 2009 | Certificate of Recognition, Elsevier's Top 10 Cited Articles for 2007-08

Borak J, Hosgood HD: Seafood Arsenic: Implications for human risk assessment. <i>Regulatory Toxicology and Pharmacology</i> 2007; 47:204-212 |
| 2010 | Fellow of the Academy of Toxicological Sciences |
| 2012 | Harriet Hardy Award, New England College of Occupational and Environmental Medicine

"For a physician who exemplifies the highest ideal of occupational and environmental medicine practice." |
| 2012 | Fellow of the American Industrial Hygiene Association |
| 2015 | Nominee, Inspiring Yale

Nomination by Yale Graduate & Professional Student Senate for recognition as Most Inspiring Teacher at Yale |

PROFESSIONAL CERTIFICATION:

Fellow, American College of Physicians
 Fellow, American College of Occupational and Environmental Medicine
 Fellow, Royal College of Physicians of Canada
 Fellow, Academy of Toxicological Sciences
 Diplomate, American Board of Internal Medicine
 Diplomate, American Board of Preventive Medicine

BORAK, Jonathan Benjamin

Page 3 of 26

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Diplomate, National Board of Medical Examiners
Licentiate, Medical Council of Canada

PROFESSIONAL EXPERIENCE:

CLINICAL and TEACHING ACTIVITIES

2008-Current Clinical Professor of Medicine, Yale University
2007-Current Clinical Professor of Epidemiology & Public Health, Yale University
2003-Current Adjunct Associate Professor of Medicine, Johns Hopkins University
2000-2010 Director, Yale University Interdisciplinary Risk Assessment Forum
1999-2007 Associate Clinical Professor of Epidemiology & Public Health, Yale University
1993-2008 Associate Clinical Professor of Medicine, Yale University.
1983-1993 Assistant Clinical Professor of Medicine, Yale University.
1981-1983 Clinical Instructor of Internal Medicine, Yale University.
1988-2001 Courtesy Attending Physician, Department of Emergency Medicine, Hospital of St. Raphael, New Haven, Connecticut.
1988-1998 Consulting Physician (Internal Medicine, Emergency Medicine, Toxicology), Hospital of St. Raphael, New Haven, Connecticut.
1980-1988 Director, Section of Emergency Medicine, Hospital of St. Raphael, New Haven, Connecticut.
1979-1988 Associate Attending Physician, Department of Ambulatory Services, Hospital of St. Raphael, New Haven, Connecticut.
1986 Visiting Professor, St. George's University School of Medicine, Kingstown Medical College, St. Vincent, W.I.
1978-80 Attending Physician, Department of Ambulatory Services, Mercy Hospital, Springfield, Massachusetts.
1978-79 Attending Physician, Emergency Physicians Incorporated, Chicopee, Massachusetts.

YALE UNIVERSITY TEACHING ACTIVITIES

Courses Taught: 1997-Current

1998-Current EHS 511b. Principles of Risk Assessment: Course Director
Graduate-level course listed in the School of Public Health, Department of Environmental Health Sciences. This course is also listed as a graduate-level course in the School of Forestry and Environmental Studies (F&ES 893b).
2002-2016 EHS 503a. Principles of Toxicology: Course Director
Graduate-level course listed in the School of Public Health, Department of Environmental Health Sciences. This course was also listed as a graduate-level course in the School of Forestry and Environmental Studies (F&ES 96005a).

BORAK, Jonathan Benjamin

Page 4 of 26

2012-Current EHS 575a Introduction to Occupational and Environmental Medicine: Lecturer
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health and the Department of Internal Medicine.

2011-Current EHS 573b Epidemiological Issues in Occupational and Environmental Medicine: Lecturer
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health and the Department of Internal Medicine.

2001-2010 EHS 551a and b. Seminar in Environmental Health: Lecturer
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health.

2005-2016 Interdisciplinary Center for Bioethics Summer Internship Program: Lecturer
International program for undergraduate and graduate students, supported by the Donaghue Medical Research Foundation

2012-2015 EHS 510a (Principles of Environmental Health): Lecturer
Graduate-level course listed in the School of School of Public Heal, Department of Environmental Health Sciences.

2014 EHS 525a (Seminar and Journal Club in Environmental Health): Lecturer
Graduate-level course listed in the School of School of Public Heal, Department of Environmental Health Sciences.

2005-2016 EPH 500 (Introduction to Epidemiology and Public Health): Lecturer
Graduate-level (second-year required) course in the School of Medicine.

2006-2012 Faculty Advisor, Yale Center for Environmental Law & Policy
The Center is a joint initiative between the Yale School of Forestry & Environmental Studies and the Yale Law School.

2005-2015 EHS 508a Assessing Exposures to Environmental Stressors: Lecturer
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health.

2008-2010 FES 96017. Fundamentals of Environmental Health: Lecturer
Graduate-level course listed in the School of Forestry and Environmental Studies.

2002-2007 EHS 510b. Fundamentals of Environmental Health & Risk Assessment: Lecturer
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health.

2000-2003 EHS 580a. Special Topics in Society and Risk Assessment: Course Director
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health.

1999-2002 EHS 509a. Environmental Toxicology: Lecturer
Graduate-level course listed in the School of Medicine, Department of Epidemiology and Public Health, and cross-listed in the School of Forestry and Environmental Studies.

Thesis and Dissertation Committees

2017 Primary Advisor: Jie Wu: "Toxicology and Pharmacokinetics of Perfluorooctanoic Acid (PFOA)". Thesis for MPH in Environmental Health Sciences, Yale School of Public Health.

BORAK, Jonathan Benjamin

Page 5 of 26

- 2015 Primary Advisor: Shae Selix: "Critical Review and Stratified Meta-Analysis of Lung Cancer Risk in Petroleum Refinery Workers. Thesis for MPH in Environmental Health Sciences, Yale School of Public Health.
- 2012 Committee Member. Sanjay Baliga: "Assessing the Capacity of Countries to Manage the Human Health and Ecosystem Risk of Chemicals: Using Stakeholder Input to Evaluate Risk Management Programs in Tanzania". Dissertation for PhD in Environmental Policy, Yale School of Forestry and Environmental Studies.
- 2008 Primary Advisor: Catherine Salipante-Zaidel: "Markov Chain Analysis of the Use of Beryllium Lymphocyte Proliferation Tests for Screening of Asymptomatic Individuals". Masters Thesis for MEE, Yale School of Forestry and Environmental Studies.
- 2005 Primary Advisor: H. Dean Hosgood: "Silica and Lung Cancer: Industrial Hygiene Methods and Mathematical Modeling Revisited". Thesis for MPH in Environmental Health Sciences, Yale School of Medicine
- 2003 Committee Member: Carlos Gonzalez: "The Beef Hormone Ban in the European Union and the Role of the WTO in Resolving Scientific Barriers to Trade". Dissertation for PhD in Environmental Policy, Yale School of Forestry and Environmental Studies.
- 2002 Primary Advisor: Susan Chemerynski: "Methodological Uncertainties in the Exposure Assessment of Diesel Particulate Matter: Implications for Risk Assessment". Thesis for MPH in Environmental Health Sciences, Yale School of Medicine
- 2002 Committee Member: Montira Pongisiri: "Institutional Capacity to Assess and Manage Risk-Tradeoffs: The DDT/Malaria Dilemma". Dissertation for PhD in Environmental Policy, Yale School of Forestry and Environmental Studies

Other Yale Activities

2013-Current Member, Clinical Competency Committee, Yale Program in Occupational and Environmental Medicine

This committee is responsible for the review and evaluation of the professional development of medical residents and fellows in Yale's OEM training program.

2013 Faculty Mentor, Edward A. Bouchet Undergraduate Fellowships Program

This program provides financial and academic research support to minority students at Yale College who have determined to pursue careers in academics.

2002-2010 Director, Yale Interdisciplinary Risk-Assessment Forum

This program, a cooperative project underwritten by Yale's Institution for Social and Policy Studies, School of Public Health, and School of Forestry and Environmental Studies, organized and hosted a regular schedule of lectures, seminars and other educational activities

ORGANIZATIONAL ACTIVITIES

United States Environmental Protection Agency

1996-2006 National Advisory Committee to Develop Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL)

BORAK, Jonathan Benjamin

Page 6 of 26

National Research Council (National Academy of Sciences)

2001-2005 Subcommittee on Toxicologic Assessment of Low-Level Exposures to Chemical Warfare Agents

National Institute for Occupational Safety and Health

2011-2012 External Review Panel – “Criteria for a Recommended Standard: Occupational Exposures to Diacetyl and 2,3-Pentanedione”

National Institute of Environmental Health Sciences

2009-2010 Review Panel – RFA ES-09-001 – Partnership for Environmental Public Health

American College of Occupational and Environmental Medicine

1999-2002 Board of Directors
 1999-2002 Board Finance Committee
 1993-Current Council on Scientific Affairs (Chair 1999-2012)
 2008-Current Council on Public Affairs
 2003-2004 Planning Committee, 2005 American Occupational Health Conference
 1997-2002 Council on Conferences (Associate Chair 1998-2002)
 1993-1999 Course Director, Core Curriculum in Environmental Medicine.
 1992-2008 Committee on Environmental Medicine (Chair 1993-96)
 1993-2000 Committee on Medical Surveillance (Chair 1998-2000)
 1996-1998 Seminar Chair, 1998 American Occupational Health Conference
 1992-1993 Scientific Chair, 1993 State-of-the-Arts Conference
 1997-2002 Committee on Conferences (Associate Chair 1997-2002)
 1995-2006 Committee on Government Affairs
 1992-1997 Committee for Liaison with Government Agencies
 1995-1997 Committee on Distance Learning (Associate Chair 1996-1997)
 1993-1996 Occupational Medicine Self-Assessment Program
 1993-1997 House of Delegates

International Dose-Response Society (previously the International Hormesis Society)

2005-Current Executive Committee

Cyanide Poisoning Treatment Coalition

2006-2009 Board of Directors

American Industrial Hygiene Association

1990-2000 Committee on Emergency Response Planning
 2010-Current Committee on Occupational Medicine

Connecticut Academy of Science and Engineering

2010-2010 CASE Artificial Turf Study Peer Review Committee

Connecticut State Medical Society

1994-1996 Section of Preventive Medicine (Chairman 1994-96)
 1983-1994 Committee on Emergency Medical Services (Chairman 1985-1988)
 1987-1992 Committee on Organ and Tissue Transfer

Occupational and Environmental Medical Association of Connecticut

1992-1998 Board of Directors
 1994-1995 President
 1993-1994 President-Elect
 1992-1993 Secretary-Treasurer

BORAK, Jonathan Benjamin

Page 7 of 26

American College of Emergency Physicians

1992-1994 Liaison to ATSDR Case Studies in Environmental Medicine
 1991-1994 Section of Disaster Medicine (Chair, Hazardous Materials Subsection 1991-1994)
 1988-1990 National Councilor (Alternate)
 1987-1988 National Committee on Chapter Grants
 1984-1986 National Committee on Bio-Ethics

Connecticut Poison Control Center

1993-1999 Medical Advisory Committee

American College of Surgeons

1984-1988 Associate Member, Connecticut Committee on Trauma

American Heart Association

1981-2000 Instructor, Advanced and Basic Cardiac Life Support
 1985-1987 National Faculty for Advanced Cardiac Life Support
 1980-1984 State Chairman, Advanced Cardiac Life Support
 1980-1984 State Emergency Cardiac Care Task Force

Connecticut College of Emergency Physicians

1986-1987 President
 1980-1990 Board of Directors

Connecticut Red Cross

1987-1992 Medical Advisory Committee on Blood Programs

Connecticut Dept of Health Services, Office of Emergency Medical Services

1985-1988 Helicopter Over-site Committee (Chairman, Patient Care Review)
 1987-1988 Trauma Network Committee

Emergency Medical Systems Council of South Central Connecticut

1980-1988 Medical Advisory Committee (Chairman 1987-1988)

New Haven County Medical Association

1984 Committee on Consumer Protection

Town of North Haven, Connecticut

1987-1995 Local Emergency Planning Committee (Chairman 1988-1990)

Town of Branford, Connecticut

1982-84 Ambulance Commissioner

Shirley Frank Foundation, New Haven, Connecticut

1983-1989 Board of Directors
 1983-1989 Chairman, Medical Treatment/Quality Assurance Committee
 1985-1989 Executive Committee

Alcohol Services Organization of South Central Connecticut

1981-1984 Board of Directors

Columbus House Shelter, New Haven, Connecticut

1981-83 Founding Member, Board of Directors

World Figure Skating Championships

1980-81 Medical Director

BORAK, Jonathan Benjamin

Page 8 of 26

Canadian Association of Interns and Residents

1973-75 Board of Directors

Federation des Medecins Residents du Quebec

1973-75 Treasurer

Canadian National Committee on Physician Manpower

1973-74 Committee Member

PROFESSIONAL LICENSURE:

State of Connecticut #19428

PROFESSIONAL ORGANIZATIONS and SOCIETIES:

American College of Physicians
American College of Emergency Physicians
American College of Occupational and Environmental Medicine
American College of Preventive Medicine
Royal College of Physicians of Canada
Society for Toxicology
Society for Risk Analysis
Society of Occupational Medicine (London)
American Industrial Hygiene Association
Association of Occupational and Environmental Clinics
Medichem
International Hormesis Society
Ramazzini Society
Connecticut State Medical Society
Occupational and Environmental Medical Association of Connecticut
New Haven County Medical Society
New Haven Medical Association

PUBLICATIONS and EDITORIAL ACTIVITIES:

Editorial Activities

2004-Current Editorial Board, Journal of Occupational and Environmental Medicine

2003-Current Editorial Board, Journal of Occupational and Environmental Hygiene

Guest Editor: State of the Science of Occupational Exposure Limit Methods and Guidance; JOEH 12(Supplement 1): 2015

2007-Current International Advisory Board, Occupational Medicine

1999-2004 Editorial Board, American Industrial Hygiene Association Journal

1997-2004 Associate Editor, OEM: Occupational and Environmental Medicine Report

1992-Current Editorial Reviewer: American Journal of Industrial Medicine; American Journal of Critical Care and Respiratory Medicine; Annals of Occupational Hygiene; Annals of Emergency Medicine; Critical Reviews in Toxicology; Dose Response; Human and Ecological Risk Assessment; Inhalation Toxicology; Journal of the Air & Waste Management Association; Nonlinearity in Biology, Toxicology and

BORAK, Jonathan Benjamin

Page 9 of 26

Medicine; Proceedings of the American Thoracic Society; Psychological Reports; Regulatory Toxicology and Pharmacology; Toxicology and Applied Pharmacology; Toxicology & Industrial Health

- 1991-2004 Editorial Board, OEM: Occupational and Environmental Medicine Report
- 2011-2012 Peer Reviewer, NIOSH: "Criteria for a Recommended Standard: Occupational Exposures to Diacetyl and 2,3-Pentanedione"
- 1988-2010 Peer Reviewer, Case Studies in Environmental Medicine, US Agency for Toxic Substances and Disease Registry, Atlanta, Georgia
- 2006-2010 Peer Reviewer, Medical Management Guidelines for Acute Chemical Exposures, US Agency for Toxic Substances and Disease Registry, Atlanta, Georgia
- 1991-92 Peer Reviewer, Toxicology Profiles, US Agency for Toxic Substances and Disease Registry, Atlanta, Georgia
- 1979-81 Consulting Editor, Update Publications, Ltd., London

Books and Monographs

- Borak J, Callan M, Abbott W: Hazardous Materials Exposure: Emergency Response and Patient Care. Englewood Cliffs, NJ: Prentice Hall, 1991.
- Borak J, Callan M, Abbott W: Hazardous Materials Exposure: Emergency Response and Patient Care - Instructor's Manual. Englewood Cliffs: Prentice Hall, 1991.
- Levy B, McCunney RM, Adamowski SE, Borak J, Halperin W, McDiarmid MA, Orris P: Occupational Medicine Self-Assessment Program (3rd Ed). Arlington Heights: American College of Occupational and Environmental Medicine, 1993.
- Medical Management Guidelines for Acute Chemical Exposures. (Principal Authors: Borak J, Olsen K, Sublet V). Atlanta: Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, 1994.
- Borak J (ed): Core Curriculum in Environmental Medicine. Arlington Heights, IL: American College of Occupational and Environmental Medicine, 1994.
- Russi M, Borak J: The OSHA Asbestos Standard: A Medical Compliance System. New Haven, CT: AEGIS Healthcare Systems, 1995.
- Borak J (Guest Editor): Amler R, Amler S, Balk SJ, McLellan RM (Guest Contributors): Pediatric Environmental Health (ATSDR-HE-CS-2002-0002). Case Studies in Environmental Medicine, US Agency for Toxic Substances and Disease Registry, Atlanta, 2002.
- Ducatman AM, Borak J, Kaye W, Peipens L (Guest Contributors): Investigating Disease Clusters (ATSDR-HE-CS-2002-0006). Case Studies in Environmental Medicine. Atlanta: Agency for Toxic Substances and Disease Registry, 2002.
- McCunney RJ, Rountree P, Barbanel C, Borak J, Bunn W, Levin J, Harber P (ed): A Practical Approach to Occupational and Environmental Medicine (3rd Edition). Philadelphia, Lippincott Williams & Wilkins, 2003.

Book Chapters and Technical Reports

- Borak J: Training and Education of Workers and Managers. In: Levy B (ed): Air Pollution in Central and Eastern Europe. Boston: Management Sciences for Health, 1991.

BORAK, Jonathan Benjamin

Page 10 of 26

- Borak J, Callan M, Abbott W: Protection of the Health Care System. In: Tokle G (ed): Hazardous Materials Response Handbook (Second Edition). Quincy, MA: National Fire Protection Association, 1993.
- Borak J: Anion and Osmolar Gaps. In: Viccellio P (ed): Handbook of Medical Toxicology (1st edition). Boston: Little, Brown, 1993.
- Borak J: Worksite and Environmental Emergencies: Planning Requirements. In: McCunney RJ (ed): A Practical Approach to Occupational and Environmental Medicine. Boston: Little, Brown, 1994.
- Borak J: Les nouvelles normes de qualité de l'air aux Etats-Unis: bases épidémiologiques et bénéfices attendus. In: Pollution Atmosphérique Urbaine et Santé Humaine. Paris: la Société de Pneumologie de Langue Française, 1997.
- Borak J: Anion and Osmolar Gaps. In: Viccellio P (ed): Handbook of Medical Toxicology (2nd edition). Boston: Lippincott-Raven, 1998.
- McKay CA, Borak J: Chlorine. In: Haddad LM, Winchester JF, Shannon M (ed): Clinical Management of Poisoning and Drug Overdose (3rd edition). Philadelphia: Saunders, 1998.
- Borak J: Four Organic Pollutants in the Quinnipiac River: Effects on Human Health. In: Tyrrell ML (ed): Quinnipiac River Point Source Pollution: Is it Still a Problem? New Haven: Center for Coastal and Watershed Systems, Yale School of Forestry and Environmental Studies, 2000.
- Russi M, Borak J: Chemical Hazards in Health Care Workers. In: Orford R (ed): Clinics in Occupational and Environmental Medicine: Occupational Health in the Healthcare Industry. Philadelphia: W.A. Saunders, 2001; 1(2):369-395.
- Borak J: Surveillance and Monitoring for Occupational Carcinogens. In: Whysner J, Shields PG (eds): Clinics in Occupational and Environmental Medicine: Cancer in the Workplace: Agents, Mechanisms, Detection, Diagnosis, Management and Prevention. Philadelphia: W.A. Saunders, 2002; 2(4): 737-752.
- Borak J: Medical Aspects of Environmental Emergencies. In: McCunney RJ, Rountree P, Barbanel C, Borak J, Bunn W, Levin J, Harber P (eds): A Practical Approach to Occupational and Environmental Medicine (3rd Edition). Philadelphia: Lippincott Williams & Wilkins, 2003; 768-773.
- Borak J, Heywood JB, Parsley W, Pickett T, Widmer W: FY 2003 Two Hundred Bus Procurement: Expert Panel Report to Massachusetts Bay Transportation Authority. 10/14/2002
- Borak J, Pleus R: Toxicology. In: McCunney RJ, Rountree P, Barbanel C, Borak J, Bunn W, Levin J, Harber P (eds): A Practical Approach to Occupational and Environmental Medicine (3rd Edition). Philadelphia: Lippincott Williams & Wilkins, 2003; 554-570.
- Moore JS, Rose S, Borak J: Ergonomics. In: McCunney RJ, Rountree P, Barbanel C, Borak J, Bunn W, Levin J, Harber P (eds): A Practical Approach to Occupational and Environmental Medicine (3rd Edition). Philadelphia: Lippincott Williams & Wilkins, 2003; 607-623.
- Borak J, Fields C, Sirianni G: The Toxicology of Complex Mixtures. In: Luttrell WE, Jederberg WM, Still KE, Robert K (ed): Toxicology Principles for the Industrial Hygienist. Fairfax:

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Page 11 of 26

American Industrial Hygiene Association, 2008; 273-282.

Fields C, Borak J: Iodine Deficiency in Vegetarian and Vegan Diets: Evidence-Based Review of the World's Literature on Iodine Content in Vegetarian Diets. In: Preedy VR, Burrow GN, Watson RR (ed): Comprehensive Handbook on Iodine. Oxford: Academic Press, 2009; 521- 531.

Borak J: Cyanide Treatment in Fire Victims. In: American Academy of Orthopedic Surgeons: Assessment and Treatment of Trauma. Sudbury, MA: Jones & Bartlett, 2010; 196-197.

Borak J, Sirianni G: Clinical Practice of Biological Monitoring: Trichloroethylene. In: Hoffman H, Phillips S (eds): Clinical Practice of Biological Monitoring. Beverly, MA: OEM Press, 2012; 214-220.

Borak J, Fields C, Sirianni G: The Toxicology of Complex Mixtures. In: Lutrell WE, Jederberg WM, Still KE, Robert K (ed): Toxicology Principles for the Industrial Hygienist. Fairfax: American Industrial Hygiene Association, 2017; (in press)

Journal Articles

Borak J: Clinical decisions analysis [letter]. Journal of the American Medical Association, 1977; 237:641.

Borak J: *Hypertension: A Policy Perspective* by MC Weinstein and W Stason [book review]. Annals of Internal Medicine, 1977; 87:135.

Borak J: Data requirements for clinical decisions on renovascular hypertension. Clinical and Investigative Medicine, 1979; 2:105.

Meyer C, McBride WJ, Goldblatt RS, Borak J, Marignani P, Contino C, McCallum R: Flexible fiberoptic sigmoidoscopy in asymptomatic and symptomatic patients: a comparative study. Gastrointestinal Endoscopy, 1979; 25:43.

Borak J, Vasey F, Lauter S, Dorval G, Osterland CK: Immunofluorescence assay for antinuclear factor: a nonspecific test in hospitalized patients. Canadian Medical Association Journal, 1979; 121:1372.

Abstracted in: Twenty-Fifth Rheumatism Review. Atlanta: Arthritis Foundation, 1981.

Borak J, Vasey F, Lauter S, Dorval G, Osterland CK: Immunofluorescence assay for antinuclear factor: the meaning of specificity [letter]. Canadian Medical Association Journal, 1980; 123:474.

Meyer C, McBride WJ, Goldblatt RS, Borak J, Marignani P, Black HR, McCallum RW: Clinical experience with flexible sigmoidoscopy in asymptomatic and symptomatic patients. Yale Journal of Biology and Medicine, 1980; 53:345.

Borak J, Veilleux S: Does statistical training improve physician logic? Clinical Research, 1981; 29:316A.

Borak J, Veilleux S: Prophylactic lidocaine: Uncertain benefits in emergency settings. Annals of Emergency Medicine, 1982; 11:493.

Borak J, Veilleux S: Errors of intuitive logic among physicians. Social Science and Medicine, 1982; 16:1939.

Bell C, Borak J, Loeffler JR: Pneumothorax in drug abusers: A complication of internal jugular venous injections. Annals of Emergency Medicine, 1983; 12:167.

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Page 12 of 26

- Borak J, Veilleux S: Informed consent in emergency settings. Annals of Emergency Medicine, 1984; 13:731.
Reprinted in Connecticut Medicine, 1984; 48:235.
- Granata AV, Halickman JF, Borak J: Utility of military anti-shock trousers (MAST) in anaphylactic shock. Journal of Emergency Medicine, 1985; 2:349.
- Starr LM, Borak J, Waymaster S: Responding to industrial accidents requires development of disaster plan. Occupational Health and Safety, 1985; 55:19.
- Borak J: A Primer on EMS for Connecticut physicians. Connecticut Medicine, 1985; 49:657.
- Starr LM, Bush DF, Borak J, Waymaster S, Somerfield M: Emergency teams and industry have different perceptions of each other. Occupational Health and Safety, 1986; 55(June):20.
- Borak J, Bush DF, Starr L, Waymaster S: The hazards of ignorance: the EMS/Industry interface. Journal of Emergency Medical Services, 1986; 11(September):6.
- Starr LM, Bush DF, Borak J, Waymaster S: Workplace medical emergencies. The Health Psychologist, 1986; 8(2):2.
- Borak J, Starr LM: On emergency medical preparedness for industrial accidents. ECO, 1987; (March):3.
- Starr LM, Leach T, Borak J: Occupational emergencies and EMS. Journal Emergency Care and Transport, 1988; 17:46.
- Herbener D, Borak J: Cutaneous larva migrans in Northern climates. American Journal of Emergency Medicine, 1988; 6:462.
- Borak J: The Superfund Amendments and Reauthorization Act of 1986: Implications for prehospital services. Emergency Care Quarterly, 1990; 6(3):29.
- Borak J: HazMat training. Journal of Emergency Care and Transport, 1991; 20(4):44.
- Borak J: Predicting HazMat effects through exposure routes and injury mechanisms. Rescue, 1991; 4(3):62.
- Borak J: Phosgene toxicity: Review and update. Occupational and Environmental Medicine Report, 1991; 5:19.
- Borak J: Welding-related illness: New thoughts on an old malady. Occupational and Environmental Medicine Report, 1991; 5:89.
- Borak J, Sidell FC: Agents of chemical warfare. I. Sulfur mustard. Annals of Emergency Medicine, 1992; 21:303.
- Sidell FC, Borak J: Agents of chemical warfare. II. Nerve agents. Annals of Emergency Medicine, 1992; 21:865.
- Borak J: Acute acrylonitrile toxicity: Reconsideration of mechanisms and antidotes. Occupational and Environmental Medicine Report, 1992; 6:19.
- Borak J: Cadmium nephropathy: Review and update. Occupational and Environmental Medicine Report, 1992; 10:75.
- Borak J: Toxicology of glycol ethers: a quick review. Occupational and Environmental

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Page 13 of 26

Medicine Report, 1993; 7:43.

Borak J, Jaffe D: Aluminum and Alzheimer's disease. Occupational and Environmental Medicine Report, 1994; 8:3.

Borak J: Environmental Surveillance: understanding of exposure limits needed for proper job application. Occupational Health and Safety, 1994; 63(5):30.

Borak J, Russi M, Jaffe D: Criteria for significant threshold shift in occupational hearing programs: a re-evaluation. Occupational and Environmental Medicine Report, 1994; 8:49.

Borak J: Environmental Surveillance: ACGIH's Threshold Limit Values. Occupational Health and Safety, 1994; 63 (8):26.

Borak J: Environmental Surveillance: OSHA's outdated Air Contaminants system. Occupational Health and Safety, 1994; 63(12):41.

Russi M, Borak J: Special Report: Medical surveillance under the new Asbestos Standards. Occupational and Environmental Medicine Report, 1995; 9:6.

Borak J: Workplace monitoring and environmental surveillance: What's the difference? Occupational Health and Safety, 1995; 649:(4):30.

Borak J: Pharmacologic mechanism of antidotes in cyanide and nitrile poisoning (letter). Journal of Occupational and Environmental Medicine, 1995; 37:793.

Flaten TP, Pollack ES, Hill G, Borak J, Bonham GH: Aluminum and Alzheimer's disease: concluding remarks. EnvironMetrics 1995; 6:319.

Borak J: *Dioxins and Health*, edited by A Schechter [book review]. Journal of Occupational and Environmental Medicine 1995:38:305.

Borak J, Israel L: Does *in utero* exposure to PCBs cause developmental toxicity? Occupational and Environmental Report, 1997; 11:13.

Borak J, Wise JP: DNA-Protein crosslinks as biomarkers of formaldehyde exposure. International Journal of Occupational and Environmental Health, 1997; 3:307.

Borak J: Chromium valence and chromium species: A carcinogenicity dilemma (editorial). Occupational and Environmental Medicine Report, 1997; 11:93.

Borak J, Pastides H, Van Ert M, Russi M, Herzstein J: Exposure to MTBE and acute human health effects: a critical literature review. Human and Ecological Risk Assessment, 1998; 4:177.

Borak J, Wise JP: Does aluminum exposure of pregnant animals lead to accumulation in mothers or their offspring? Teratology 1998; 57:127.

Borak J, Silverstein BD: Emergency response plans: the benefits of integration. Occupational Hazards, 1999; 61(9): 44.

Borak J, Cohen HJ, Hethmon TA: Copper exposure and metal fume fever: Lack of evidence for a causal relationship. American Industrial Hygiene Association Journal 2000; 61:832.

Borak J, Russi M, Puglisi JP: Meta-analyses [letter]. Environmental Health Perspectives, 2000; 108:A542.

Borak J, Diller WF: Phosgene exposure: Mechanisms of injury and treatment strategies. Journal of Occupational and Environmental Medicine, 2001; 43:110.

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Page 14 of 26

Borak J: Why diesel and why now? [editorial]. Occupational and Environmental Report, 2001; 15:65.

Borak J, Sirianni G, Cohen H, Chemerynski S, Jongeneelen F: Biological vs. ambient exposure monitoring of creosote facility workers. Journal of Occupational and Environmental Medicine, 2002; 44:310.

Reprinted in: Journal of the Institution for Social and Policy Studies. 2003; 4:7.

Recipient of the 2003 **Adolph G. Kammer Merit in Authorship Award** of the American College of Occupational and Environmental Medicine

Cohen HJ, Borak J, Hall T, Sirianni G, Chemerynski S: Exposure of miners to diesel particulate matter in underground non-metal mines. American Industrial Hygiene Association Journal, 2002; 63:651.

Cohen, HJ, Sirianni G, Chemerynski S, Wheeler R, Borak J: Observations on the suitability of the Aethalometer for vehicular and workplace monitoring. Journal of the Air & Waste Management Association, 2002; 52:1258.

Borak J, Sirianni G, Cohen HJ, Chemerynski S, Wheeler R: Comparison of NIOSH 5040 method vs. Aethalometer to monitor diesel particulate in school buses and work sites. American Industrial Hygiene Association Journal, 2003; 64:260.

Sirianni G, Chemerynski S, Cohen HJ, Wheeler R, Borak J: Sources of Interferences in field studies of diesel exhaust emission. Applied Occupational and Environmental Hygiene, 2003; 18:591.

Fiellin M, Chemerynski S, Borak J: Editorial: Race, ethnicity and the SEER Database. Medical and Pediatric Oncology, 2003; 40:413.

Borak J, Fiellin M, Chemerynski S: Who is Hispanic? Implications for epidemiological research in the United States. Epidemiology, 2004; 15:240-244.

Borak J: Adequacy of iodine nutrition in the United States. Connecticut Medicine, 2005; 69:73-77.

Borak J, Slade MD, Russi M: Risks of brain tumors in rubber workers: a meta-analysis. Journal of Occupational and Environmental Medicine 2005; 47:294-298.

Fields C, Dourson M, Borak J: Iodine-Deficient Vegetarians: A hypothetical perchlorate-susceptible population? Regulatory Toxicology and Pharmacology, 2005; 42:37-46.

Borak J: Neonatal hypothyroidism due to maternal vegan diet. Journal of Pediatric Endocrinology and Metabolism 2005; 18:621.

Fields C, Borak J: *Toxicology of the Kidney* by JB Tarloff and LH Lash [book review]. Journal of Occupational and Environmental Medicine 2005; 47:1317-1318.

Borak J: The Beryllium Occupational Exposure Limit: Historical perspectives and current inadequacy. Journal of Occupational and Environmental Medicine 2006; 48:109-116.

Borak J, Sirianni G: Hormesis: Implications for cancer risk assessment. Dose Response 2005; 3:443-451.

Borak J, Woolf SH, Fields CA: Use of BeLPT for screening of asymptomatic individuals: An evidence-based assessment. Journal of Occupational and Environmental Medicine 2006; 48:937-948.

BORAK, Jonathan Benjamin

Page 15 of 26

Borak J: The Beryllium Occupational Exposure Limit: Historical origin and current inadequacy: Author's Response. Journal of Occupational and Environmental Medicine 2006; 48:998-1001.

Borak J, Hosgood HD: Seafood Arsenic: Implications for human risk assessment. Regulatory Toxicology and Pharmacology 2007; 47:204-212.

Recipient of **Certificate of Recognition: Elsevier's Top 10 Cited Articles of 2007-08**

Borak J, Woolf SH, Fields CA: Use of BeLPT for screening of asymptomatic individuals: Author's Response [letter]. Journal of Occupational and Environmental Medicine 2007; 49:358-9.

Borak J, Sirianni G: Studies of Self-pollution in Diesel School Buses: Methodological Issues. Journal of Occupational and Environmental Hygiene 2007; 4:660-668.

Sirianni G, Hosgood HD, Slade MD, Borak J: Particle size distribution and particle size-related silica content in granite quarry dust. Journal of Occupational and Environmental Hygiene 2008; 5:279-285.

Russi MB, Borak JB, Cullen MR: An examination of cancer epidemiology studies among populations living close to toxic waste sites. Environmental Health 2008; 7:32.

Slade MD, Borak J: *Statistical Evidence in Medical Trials: What do the data really tell us?* By SD Simon [book review]. Journal of Occupational and Environmental Medicine 2008; 50:602.

Borak J: *Nanotoxicology: Characterization, Dosing and Health Effects*. By NA Monteiro-Riviere and CL Tran [book review]. Journal of Occupational and Environmental Medicine 2009; 51:620.

Borak J: Five classic articles in Public Health. Yale Journal of Biology and Medicine 2010; 83:43-45.

Sirianni G, Borak J: How clean is "Clean"? Regulations and standards for workplace clothing and personal protective equipment. Journal of Occupational and Environmental Medicine 2010; 52:190-196.

Borak J, Fields C, Andrews LS, Pemberton MA: Methyl Methacrylate and respiratory sensitization: A critical review. Critical Reviews in Toxicology 2011; 41:230-268.

Borak J, Bunn WB, Chase GR, Hall TA, Head JH, Hesterberg TW, Sirianni G, Slavin TJ: Comments on the Diesel Exhaust in Miners Study [Letter]. Annals of Occupational Hygiene, 2011; 55:339-342.

Borak J: Obesity and the Work Place [editorial]. Occupational Medicine, 2011; 61: 220-222.

Fields C, Borak J: *Heavy Metals: A Rapid Clinical Guide to Neurotoxicity and other Common Concerns*. By KR Spaeth, AJ Tsismenakis, SN Kales [book review]. Journal of Occupational and Environmental Medicine 2011; 53:587.

Borak J, Salipante-Zaidel C, Slade MD, Fields CA: Mortality Disparities in Appalachia: Reassessment of Major Risk Factors. Journal of Occupational and Environmental Medicine 2012; 54:146-156.

Borak J, Slade MD, Allen RA, Salipante-Zaidel C, Fields CA: Ecological Bias and Data Entry Errors: Response to Hendryx and Ahern. Journal of Occupational and Environmental Medicine 2012; 54:770-773.

Borak J: *A Biologic Approach to Environmental Assessment and Epidemiology*. By TJ Smith and

BORAK, Jonathan Benjamin

Page 16 of 26

D Kriebel [book review]. Journal of Occupational and Environmental Medicine 2012; 54:1040-1041.

Dworak JJ, Roberts DW, Calter MA, Fields CA, Borak J: Is Diacetyl a Respiratory Sensitizer? A Reconsideration using QSAR, QMM and Competition Experiments. Chemical Research in Toxicology, 2013; 26:631-633. (<http://dx.doi.org/10.1021/tx400097v>).

Roberts DW, Calter MA, Borak J, Fields CA, Letter to the editor. Food and Chemical Toxicology, 2014; 70:260-62. (<http://dx.doi.org/10.1016/j.fct.2014.05.013>).

Borak J: *The Norm Chronicles: Stories and Numbers about Danger and Death* by M Blastland and D Spiegelhalter [book review]. Journal of Occupational and Environmental Medicine 2015; 57:e11.

Borak J, Brosseau LM: The Past and Future of Occupational Exposure Limits. Journal of Occupational and Environmental Hygiene 2015; 12:S1-S3.

Borak J, Lefkowitz RY: Bronchial Hyperresponsiveness: In-Depth Review. Occupational Medicine (London) 2016; 66:95-105. (doi: 10.1093/occmed/kqv158).

Borak J: Chronic Beryllium Disease: The Search for a Dose-Response. Journal of Occupational and Environmental Medicine 2016; 58:e355-361.

Committee and Group Publications

Bioethics Committee, American College of Emergency Physicians: Medical, moral, legal, and ethical aspects of resuscitation for patients who have minimal ability to function or ultimately survive. Annals of Emergency Medicine, 1985; 14:919.

American Hospitals in Transition: Business Implications and Strategic Considerations for Medical Suppliers. New York: Channing, Weinberg & Co., 1984.

Committee on Organ and Tissue Transfers, Connecticut State Medical Society. HIV testing of transfusion recipients. Connecticut Medicine, 1990; 54:217.

Badon SJ, Cable RG and Committee on Organ and Tissue Transfers, Connecticut State Medical Society. Yersinia enterocolitica contamination of blood. Connecticut Medicine, 1992; 56:287.

Emergency Response Planning Committee, American Industrial Hygiene Association: The AIHA 1996 Emergency Response Planning Guidelines and Workplace Environmental Exposure Level Guides Handbook. Fairfax: AIHA, 1996.

World Health Organization. Environmental Health Criteria 194: Aluminium. Geneva: World Health Organization, International Program on Chemical Safety, 1997.

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Page 17 of 26

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Page 18 of 26

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Page 19 of 26

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Page 20 of 26

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Page 21 of 26

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Page 24 of 26

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BORAK, Jonathan Benjamin

Page 25 of 26

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State-of-the-Art Conference, American College of Occupational and Environmental Medicine, Dallas, 1993

American Occupational Health Conference, American College of Occupational and Environmental Medicine, Chicago, 1994

American Occupational Health Conference, American College of Occupational and Environmental Medicine, Las Vegas, 1995

American Occupational Health Conference, American College of Occupational and Environmental Medicine, San Antonio, 1996

American Occupational Health Conference, American College of Occupational and Environmental Medicine, Orlando, 1997

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BORAK, Jonathan Benjamin

Page 26 of 26

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Newtown Square, PA (Sponsored by ARCO Chemical Company), 1989.

Hospital of St. Raphael, New Haven (Sponsored by Connecticut ACEP), 1989.

Rhode Island Hospital, Providence (Sponsored by Rhode Island ACEP), 1990.

Pre-Conference Seminar, Disaster '91: The International Disaster Management Conference; Orlando, 1991.

Seattle (Sponsored by Washington ACEP), 1991

Concord, MA (Sponsored by Emerson Hospital), 1991.

Concord, NH (Sponsored by Harvard School of Public Health), 1992.

Boston, MA, (Sponsored by Conference of Boston Teaching Hospitals), 1992

Pittsburgh, PA (Sponsored by Allegheny County Health Department), 1994.

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(05/17)

Exhibit B
Jonathan Borak, MD

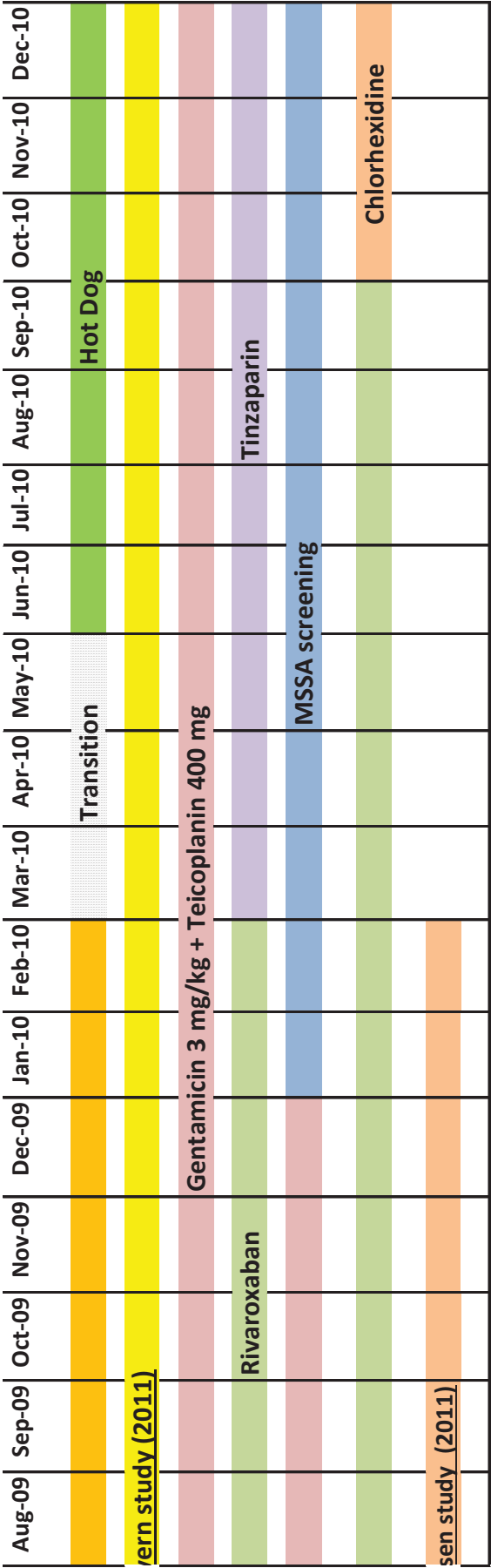
Deposition and Trial Testimony

To the best of my recollection, the following summarizes all deposition and court testimony that I have provided from January 1, 2013 thru June 1, 2017

Stults v. American Popcorn Co. et al. (US District Court, Northern District of Iowa)	Deposition 10/17/13
In Re: World Trade Center Lower Manhattan Disaster Site Litigation (US District Court, Southern District of New York)	Deposition 11/07/14
Cabot Corporation and Cabot Corporation v. Aearo Technologies and Aearo LLC. (Superior Court of Massachusetts)	Deposition 06/04/15
Secretary of Labor (MSHA) v. Klondex Midas Operations (Pittsburgh, Pennsylvania)	Deposition 03/15/17

Oct-07 thru Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09	Jun-09	Jul-09
										Bair Hugger			
											Duration of the McGovern		
	Gentamicin 4.5 mg/kg												
	Tinzaparin												
	No MSSA screening												
	No Chlorhexidine												
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Timeline for McGovern Study and Wansbeck OR Procedures (page 2)



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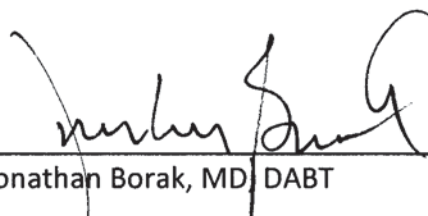
Supplemental Report of Jonathan Borak, MD, DABT

September 8, 2017

Since providing my expert report in the *In re Bair Hugger Patient Warming Devices Products Liability Litigation* dated June 2, 2017, I have had the opportunity to review the recent "Information about the Use of Forced Air Thermal Regulating Systems – Letter to Health Care Providers" FDA communication dated August 30, 2017. This FDA Letter to Health Care Providers reports that the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection, and recommends the continued use of forced air thermal regulating systems.

The August 30, 2017 Letter to Health Care Providers is consistent with my expert opinions expressed in my June 2, 2017 report, does not change any of my expert opinions, and I intend to rely on and may refer to this Letter to Health Care Providers at the time of trial in support of my existing opinions.

I certify, under penalty of perjury, that my statements in this supplemental report, executed on September 8, 2017, are true and correct.


Jonathan Borak, MD DABT

JONATHAN BORAK & COMPANY, INC.

Specialists in Occupational & Environmental Health

I certify under penalty of perjury that the statements in my expert report dated June 2, 2017 are true and correct. Executed on September 11, 2017.

Jonathan Borak, MD, DABT

EXHIBIT DX4

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

DEPOSITION OF JONATHAN BORAK
VOLUME I, PAGES 1 - 251
JULY 20, 2017

(The following is the deposition of JONATHAN BORAK, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 8:09 o'clock a.m., July 20, 2017.)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 2	Page 4
<p>1 APPEARANCES:</p> <p>2 On Behalf of the Plaintiffs:</p> <p>3 Jan M. Conlin</p> <p>4 CIRESI CONLIN L.L.P.</p> <p>5 225 South 6th Street, Suite 4600</p> <p>6 Minneapolis, Minnesota 55402</p> <p>7 On Behalf of Defendants:</p> <p>8 Corey L. Gordon</p> <p>9 BLACKWELL BURKE P.A.</p> <p>10 431 South Seventh Street, Suite 2500</p> <p>11 Minneapolis, Minnesota 55415</p> <p>12 ALSO APPEARING:</p> <p>13 Ronald M. Huber, Videotechnician</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 replacement, before and after</p> <p>2 the introduction of rivaroxaban,</p> <p>3 by Jensen, et al 145</p> <p>4 16 Article in Health Devices,</p> <p>5 Force-Air Warming and</p> <p>6 Surgical Site Infections 154</p> <p>7 17 Article, Wound Complications</p> <p>8 Following Rivaroxaban Administra-</p> <p>9 tion, by Jameson, et al 154</p> <p>10 18 Reed deposition transcript,</p> <p>11 December 4, 2016 161</p> <p>12 19 Article, Chlorhexidine-Alcohol</p> <p>13 versus Povidone-Iodine for</p> <p>14 Surgical-Site Antisepsis, by</p> <p>15 Darouiche, et al 170</p> <p>16 20 Article, Preventing Surgical-</p> <p>17 Site Infections in Nasal</p> <p>18 Carriers of Staphylococcus</p> <p>19 aureus, by Bode, et al 175</p> <p>20 21 Article, Effects of preoperative</p> <p>21 warming on the incidence of</p> <p>22 wound infection after clean</p> <p>23 surgery: A randomised controlled</p> <p>24 trial, by Melling, et al 190</p> <p>25 22 Article, Prophylactic antibiotics</p>
Page 3	Page 5
<p>1 INDEX</p> <p>2 EXHIBITS DESCRIPTION PAGE MARKED</p> <p>3 Ex 1 Expert report of Jonathan</p> <p>4 Borak 7</p> <p>5 2 Borak curriculum vitae 8</p> <p>6 3 Jonathan Borak & Company website</p> <p>7 download 39</p> <p>8 4 Article, Mortality Disparities in</p> <p>9 Appalachia, by Borak, et al 46</p> <p>10 5 E-mail sent September 06, 2002 54</p> <p>11 6 Exhibit B to Borak's expert</p> <p>12 report 61</p> <p>13 7 Kurz deposition excerpt, January</p> <p>14 12, 2017 76</p> <p>15 8 E-mail, 3M00580475 90</p> <p>16 9 510(k) Summary of Safety &</p> <p>17 Effectiveness, January 10,</p> <p>18 1996, 3MBH00047382-3 94</p> <p>19 10 E-mail string, 3MBH00024633-4 113</p> <p>20 11 E-mail string, 3MBH00544754-5 119</p> <p>21 12 E-mail string, 3MBH00132501-2 124</p> <p>22 13 E-mail string, 3MBH00130429-32 126</p> <p>23 14 E-mail string, 3MBH01330587-92 128</p> <p>24 15 Article, Return to theatre</p> <p>25 following total hip and knee</p>	<p>1 in elective hip and knee</p> <p>2 arthroplasty, by Hickson, et al 193</p> <p>3 23 Article, Implementing effective</p> <p>4 SSI surveillance, by Gillson,</p> <p>5 et al 195</p> <p>6 24 Article, Surveillance of surgical</p> <p>7 site infections in NHS hospitals</p> <p>8 in England, 2015/16 198</p> <p>9 25 Article, Staphylococcus aureus</p> <p>10 Screening and Decolonization in</p> <p>11 Orthopaedic Surgery and Reduction</p> <p>12 of Surgical Site Infections, by</p> <p>13 Chen, et al 203</p> <p>14 26 Centers for Disease Control and</p> <p>15 Prevention Guidelines for the</p> <p>16 Prevention of Surgical Site</p> <p>17 Infection, 2017 204</p> <p>18 27 McGovern deposition excerpt,</p> <p>19 January 4, 2017 215</p> <p>20 28 McGovern deposition excerpt,</p> <p>21 January 5, 2017 230</p> <p>22 29 Nachtsheim deposition excerpt,</p> <p>23 November 29, 2016 236</p> <p>24 30 Article, The Environment and</p> <p>25 Disease: Association or</p>

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

<p style="text-align: right;">Page 6</p> <p>1 Causation? by Hill 239</p> <p>2</p> <p>3</p> <p>4 WITNESS EXAMINATION BY PAGE</p> <p>5 Jonathan Borak Ms. Conlin 7</p> <p>6 Mr. Gordon 240</p> <p>7 Ms. Conlin 245</p> <p>8 Mr. Gordon 246</p> <p>9 Ms. Conlin 247</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 8</p> <p>1 BY MS. CONLIN:</p> <p>2 Q. I've handed you a copy of -- or what's been</p> <p>3 marked as Borak Deposition Exhibit No. 1. Is that</p> <p>4 your expert report in this case?</p> <p>5 A. That is correct.</p> <p>6 Q. And --</p> <p>7 (Exhibit 2 was marked for</p> <p>8 identification.)</p> <p>9 BY MS. CONLIN:</p> <p>10 Q. I've handed you, Dr. Borak, what's been</p> <p>11 marked as Borak Deposition Exhibit No. 2. Is this a</p> <p>12 copy of your CV?</p> <p>13 A. I'm sorry, what was your question?</p> <p>14 Q. Is this a copy of your CV?</p> <p>15 A. Yeah. There's several more recent</p> <p>16 publications.</p> <p>17 Q. Okay. Do you want to, if you know, name</p> <p>18 those, please.</p> <p>19 A. The names are long. They both have to do</p> <p>20 with elemental mercury exposure. They have just been</p> <p>21 published in the last week in Critical Reviews in</p> <p>22 Toxicology.</p> <p>23 Q. Okay. Other than those additions, to the</p> <p>24 best of your knowledge is Exhibit 2 correct and</p> <p>25 accurate?</p>
<p style="text-align: right;">Page 7</p> <p>1 PROCEEDINGS</p> <p>2 (Witness sworn.)</p> <p>3 JONATHAN BORAK</p> <p>4 called as a witness, being first duly sworn,</p> <p>5 was examined and testified as follows:</p> <p>6 ADVERSE EXAMINATION</p> <p>7 BY MS. CONLIN:</p> <p>8 Q. Good morning, Professor Borak. Is it --</p> <p>9 Do you go by Dr. Borak or Professor Borak?</p> <p>10 A. I -- I guess I'm more comfortable with</p> <p>11 doctor.</p> <p>12 Q. Okay.</p> <p>13 A. I've been a doctor for longer.</p> <p>14 Q. Can you spell your last name for the record,</p> <p>15 please -- or actually your full name.</p> <p>16 A. Jonathan, J-o-n-a-t-h-a-n, Benjamin,</p> <p>17 B-e-n-j-a-m-i-n, Borak, B-o-r-a-k.</p> <p>18 MS. CONLIN: We can mark that. Do you want</p> <p>19 a copy?</p> <p>20 MR. GORDON: Are you using new numbering</p> <p>21 for --</p> <p>22 MS. CONLIN: Yeah. We'll go with Borak</p> <p>23 Exhibit 1.</p> <p>24 (Exhibit 1 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 9</p> <p>1 A. I -- I think so, yes.</p> <p>2 Q. Okay. I'd like to direct your attention</p> <p>3 back to your expert report in this case dated June</p> <p>4 2nd, 2017 that has been marked as Exhibit 1. I'd like</p> <p>5 to direct your attention, Dr. Borak, to page 23 of</p> <p>6 that.</p> <p>7 Do you have it in front of you, sir?</p> <p>8 A. I do.</p> <p>9 Q. Okay. I'd like to direct your attention to</p> <p>10 paragraph 74c --</p> <p>11 A. Yes.</p> <p>12 Q. -- where you opine, "The McGovern report</p> <p>13 relied on truncated and incorrectly tabulated data.</p> <p>14 When those irregularities are corrected, the study</p> <p>15 data do not provide evidence that BH" -- Bair</p> <p>16 Hugger -- "is associated with a significant increase</p> <p>17 in SSL."</p> <p>18 That's your opinion; correct?</p> <p>19 A. You read that correctly, yes.</p> <p>20 Q. And is that your opinion?</p> <p>21 A. That's my opinion.</p> <p>22 Q. Okay. And is that your opinion today?</p> <p>23 A. That is my opinion today.</p> <p>24 Q. Okay. Have you reviewed anything since the</p> <p>25 filing of your report on June 2nd of this year?</p>

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<p style="text-align: right;">Page 10</p> <p>1 A. Yes.</p> <p>2 Q. What have you reviewed?</p> <p>3 A. I have reviewed a recent publication by Dr.</p> <p>4 Augustine.</p> <p>5 Q. Okay.</p> <p>6 A. I have reviewed a number of exhibits from</p> <p>7 what I assume to have been depositions or legal</p> <p>8 proceedings related to both Augustine and Ridgeview</p> <p>9 Medical Center.</p> <p>10 Q. Okay. Anything else?</p> <p>11 A. The answer is yes, but you're going to ask</p> <p>12 me to be specific. I have looked at a number of</p> <p>13 publications related to retractions of peer-reviewed</p> <p>14 literature, I have -- I looked at much but not all of</p> <p>15 a rough draft of Dr. Holford's deposition, and I have</p> <p>16 certainly looked back in my files. Whether in the</p> <p>17 course of that I may have looked at additional</p> <p>18 articles, it is possible, but they don't come to mind.</p> <p>19 I'm not trying to withhold anything.</p> <p>20 Q. And what was the purpose for you looking at</p> <p>21 materials related to retraction of peer-reviewed</p> <p>22 articles?</p> <p>23 A. A question arose in my mind based on a</p> <p>24 statement made at least once and possibly multiple</p> <p>25 times by Dr. Samet, who defended reliance upon</p>	<p style="text-align: right;">Page 12</p> <p>1 MR. GORDON: Sure.</p> <p>2 Q. Directing your attention back to paragraph</p> <p>3 74c and your opinion that use of Bair Hugger is not</p> <p>4 associated with an increased risk in SSIs, how do you</p> <p>5 define "associated?"</p> <p>6 A. I think that the operative word there is</p> <p>7 "significant," and I was referring to a statistically</p> <p>8 significant association.</p> <p>9 Q. My question was a little different. How do</p> <p>10 you define "associated" as that word is used in</p> <p>11 paragraph 74c?</p> <p>12 A. I don't think that you can take the word out</p> <p>13 of the context. "Associated with a significant</p> <p>14 increase" is the statement that I made.</p> <p>15 Q. Well you understand that "association" or</p> <p>16 "associated" is an epidemiological term; correct?</p> <p>17 A. It is often used in epidemiology, correct.</p> <p>18 Q. Okay. Did you use it in an epidemiologic</p> <p>19 way in connection with your use of the term</p> <p>20 "associated" in paragraph 74c?</p> <p>21 A. Only to the extent that association implies</p> <p>22 that there is a relationship -- an apparent</p> <p>23 relationship, and the question here was whether there</p> <p>24 was a signif -- a relationship indicating a</p> <p>25 significant increase.</p>
<p style="text-align: right;">Page 11</p> <p>1 probably the McGovern study because it was a peer-</p> <p>2 reviewed paper, and there was then a discussion of</p> <p>3 some notable paper or papers that had been retracted,</p> <p>4 and I just wondered in my own head how often that</p> <p>5 occurred. I have been in situations as a member of</p> <p>6 editorial boards where it's been necessary to retract</p> <p>7 papers, and I was interested to see whether this was a</p> <p>8 very common phenomenon.</p> <p>9 Q. Okay. Did you undertake that on your own or</p> <p>10 were you requested to do that by lawyers for 3M?</p> <p>11 A. I -- I -- I initiated that on my own.</p> <p>12 Q. Okay. And you indicated you read some</p> <p>13 deposition testimony related to Ridgeview. Was that</p> <p>14 by Dr. Augustine?</p> <p>15 A. I -- I did not review deposition testimony</p> <p>16 that I'm aware of that was related to Ridgeview</p> <p>17 Medical Center, at least I don't remember it as such,</p> <p>18 but I looked at a number of documents which were</p> <p>19 either marked as exhibits or had Bates numbers on</p> <p>20 them.</p> <p>21 Q. Who provided those to you?</p> <p>22 A. Mr. Gordon.</p> <p>23 MS. CONLIN: Okay. And we'll request an</p> <p>24 updated list of documents reviewed since he offered</p> <p>25 his opinions in this case.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Okay. Would you agree with me that</p> <p>2 "association," as used by epidemiologists, states that</p> <p>3 events are said to be associated when they occur more</p> <p>4 or less frequently together than one would expect by</p> <p>5 chance?</p> <p>6 A. That's probably a -- a reasonable</p> <p>7 definition.</p> <p>8 Q. Okay. So is it your opinion that use of the</p> <p>9 Bair Hugger is associated with increased infection?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question.</p> <p>12 A. Not necessarily.</p> <p>13 Q. Okay. So use of the Bair Hugger and an</p> <p>14 infection would be by chance as opposed to something</p> <p>15 else.</p> <p>16 A. What do you mean "by chance as opposed to</p> <p>17 something else?"</p> <p>18 Q. Well, do you believe that the Bair Hugger is</p> <p>19 associated with any increased risk of infection?</p> <p>20 A. I am aware of at least one paper, the</p> <p>21 McGovern paper, and a subsequent paper which we may</p> <p>22 discuss by Augustine, which have alleged that there is</p> <p>23 such an association. I'm not aware of any other data</p> <p>24 to support that, and I have significant questions</p> <p>25 about the validity of both of those papers.</p>

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<p style="text-align: right;">Page 14</p> <p>1 Q. So it's your opinion that the use of the 2 Bair Hugger is not associated with an increased risk 3 of infection. 4 A. I believe it has not been associated outside 5 of those two papers, which I have concerns about. 6 Q. Okay. My question was a little different. 7 So you -- 8 Your opinion is that the use of the Bair 9 Hugger is not associated with an increased risk of 10 infection. 11 A. I believe there is insufficient evidence to 12 make that statement. I believe that it has been 13 associated in two problematic studies. I don't know 14 that there is sufficient evidence otherwise. 15 Q. Right. So you'd agree that it's your 16 opinion that the Bair Hugger is not associated with an 17 increased risk of infection based on your review of 18 the record. 19 A. I -- and I am sorry to seem belligerent. 20 I -- my statement is I don't believe it has been 21 associated in a meaningful way, and I say that because 22 there are these two papers, which I would challenge. 23 Q. Okay. So setting -- 24 Because you don't believe those papers are 25 accurate, you have seen no evidence to find that the</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Well, do you think that a Rubber Ducky would 2 be associated with an increased risk of infection? 3 A. I -- I doubt it, but I don't know. 4 Q. Okay. So assuming that there isn't anything 5 unusual about the Rubber Ducky, the use of the Bair 6 Hugger -- presence of the Bair Hugger in use in the 7 operation -- or in an operating room would be akin to 8 having a Rubber Ducky sitting on the table -- 9 A. I -- 10 Q. -- as it relates to an increased risk of 11 infection. 12 A. I -- I -- 13 Once again, if you would rephrase your 14 question in a different way. You keep talking about 15 this Rubber Ducky, and it's something I don't know 16 anything about. 17 Q. Well you've seen the little ducks that float 18 around in a bathtub. 19 A. Oh, I understand conceptually what you're 20 speaking about, but in context I have no knowledge at 21 all. I can't answer the question as you pose it. 22 Q. Why not? 23 A. Because I don't know what the risks are of a 24 Rubber Ducky, and there may be issues that I haven't 25 appreciated.</p>
<p style="text-align: right;">Page 15</p> <p>1 use of the Bair Hugger is associated with an increased 2 risk of infection. 3 A. Yes. Excluding those papers, I have seen no 4 such evidence. 5 Q. Okay. And when epidemiologists talk about 6 events that are said to be associated when they occur 7 more or less frequently together than one would expect 8 by chance, I would take it that your opinion is that 9 the use of a Bair Hugger would have the chance of 10 causing an infection along the same lines as a -- a 11 Rubber Ducky sitting in the OR; is that right? 12 MR. GORDON: Object to the form of the 13 question. 14 A. I think there were two elements. One of 15 them is that there is a chance -- stochastic chance of 16 something else. The other one is there are other 17 moving parts in the scenario. And if you want to say 18 that everything else is held constant, then yes, only 19 chance. 20 Q. Okay. So holding everything else constant, 21 having a Bair Hugger in use in the OR would increase 22 your chance of infection to the same extent that a 23 Rubber Ducky sitting in the OR on a table would. 24 A. I -- I don't know what risk there is to a 25 Rubber Ducky, so I can't answer your question.</p>	<p style="text-align: right;">Page 17</p> <p>1 You might ask Dr. Wenzel, who is an expert 2 in nosocomial infections. He may have experience with 3 Rubber Ducky. 4 Q. Okay. Well in any event, your view is use 5 of the Bair Hugger during a surgical procedure, such 6 as an orthopedic implant, does not increase the risk 7 of infection to a patient; correct? 8 A. No. My opinion is that I have not seen any 9 evidence that it does, outside of two studies which I 10 consider to be problematical. 11 Q. Okay. And because you're saying those 12 studies are problematic, it's your opinion that use of 13 the Bair Hugger does not increase the risk of 14 infection for a patient undergoing arthroplastic 15 surgery. 16 A. I am not aware of any evidence that it does 17 so. 18 Q. Okay. Do you consider yourself an 19 epidemiologist? 20 A. I'm a professor of epidemiology. I do a lot 21 of work at the interface step of epidemiology and 22 toxicology and other such related things, yes. 23 Q. Okay. So you do hold yourself out as an 24 epidemiologist. 25 A. I am a professor of epidemiology.</p>

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<p style="text-align: right;">Page 18</p> <p>1 Q. Okay. You have a degree in -- well let's 2 back up. 3 Are you making a distinction between saying 4 you are a professor of epidemiology and an 5 epidemiologist? 6 A. I am not a board certified epidemiologist. 7 Q. Okay. And you don't have a degree in 8 epidemiology; correct? 9 A. I do not have a specific degree in 10 epidemiology. 11 Q. Your degree is in internal medicine? 12 A. In medicine. 13 Q. Okay. Do you have any clinical experience 14 in epidemiology? 15 A. I have done epidemiology in the context of 16 occupational medical practice for years. 17 Q. Okay. And you would consider that clinical 18 experience in epidemiology? 19 A. I certainly think so. 20 Q. Would you agree -- 21 Well how would you define the field of 22 epidemiology? 23 A. I think epidemiology is the study of disease 24 in populations. 25 Q. Okay. And how would one go about</p>	<p style="text-align: right;">Page 20</p> <p>1 A. I've taken lots of statistics courses, but I 2 am not a statistician. 3 Q. Okay. Were you the one who suggested 4 Professor Holford get involved in the case? 5 A. I think I may have been the one who gave 6 Corey his name one day when Corey -- that is, Mr. 7 Gordon -- asked me for the names of some expert 8 statisticians. 9 Q. Okay. And was that because you didn't feel 10 comfortable doing statistics work in the case? 11 A. I gave the name to Mr. Gordon because he 12 asked me for the name of a world-class statistician. 13 Q. Okay. Did -- 14 Well you've read Professor Holford's report; 15 correct? 16 A. I have read his report. 17 Q. And do you feel that you, in the absence of 18 him, would have been comfortable writing the numbers 19 and doing the statistics that Professor Holford did? 20 A. I probably would not have felt as 21 comfortable as he. 22 Q. Okay. So it's on those issues you're 23 deferring to Professor Holford. 24 A. I am relying upon Professor Holford. 25 Q. Okay. Did you ever have any discussions</p>
<p style="text-align: right;">Page 19</p> <p>1 ascertaining whether an event or something causes a 2 risk to the general population? 3 A. I'd certainly do research. 4 Q. Okay. And as part of that study, I take it 5 you would attempt, as an epidemiologist, to look at 6 all the evidence associated with a particular risk of 7 an event to the general population. 8 A. In principle, that sounds right. 9 (Discussion off the stenographic record.) 10 Q. I think you mentioned this, but you're not 11 an expert in infectious disease; correct? 12 A. No, I'm not. Infectious disease is part of 13 internal medicine, but I am not boarded in -- in 14 infectious disease. 15 Q. Do you have any experience in 16 anesthesiology? 17 A. No, not particularly. 18 Q. How about normothermia or hypothermia? 19 A. I have treated both, but I don't consider 20 myself an expert in either. 21 Q. Okay. Do you consider yourself having any 22 expertise in orthopedic surgery? 23 A. I have not done surgery as a professional 24 activity after training. 25 Q. And do you consider yourself a statistician?</p>	<p style="text-align: right;">Page 21</p> <p>1 with Professor Holford during the drafting of your 2 report? 3 A. No. 4 Q. Okay. And when did you first see Professor 5 Holford's expert report? 6 A. I'm sorry, I don't remember, but it was 7 between -- 8 It was probably in May, but I don't remember 9 the date. 10 Q. Okay. And was that in draft form or final 11 form? 12 A. It may have been in draft form. I'm not 13 exactly clear. 14 Q. Okay. Did you make any comments in terms of 15 edits or suggestions in connection with the report? 16 A. No. 17 Q. Okay. 18 A. Sorry. Wait, wait. I -- I -- I corrected a 19 spelling error. 20 Q. Okay. But other than that, you took the 21 report and that was, as we'll go through, incorporated 22 in part into some of the things that you have 23 testified to. 24 A. I am not aware that I suggested to Professor 25 Holford that he change anything.</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. Okay. Setting that aside, my question is: 2 You looked at that for the purposes of incorporating 3 portions or reliance on portions of Professor 4 Holford's report in your report that's been marked 5 as -- 6 A. Yes, that's correct. 7 Q. -- Borak -- 8 A. That's correct. 9 Q. -- Deposition Exhibit No. 1. 10 Okay. Now you and Professor Holford were at 11 a May 8th meeting in Washington? 12 A. We were at a meeting. I'm not sure it was 13 May 8th. But yes, -- 14 Q. Okay. 15 A. -- that meeting in Washington. 16 Q. And who else was present? 17 A. Mr. Gordon and Dr. Wenzel. 18 Q. Okay. 19 A. I don't think there was anybody else. 20 Q. Okay. And had you met Dr. Wenzel before? 21 A. No. 22 Q. Okay. Did you know of him or of his work? 23 A. I know his name. 24 Q. From what? 25 A. The medical literature.</p>	<p style="text-align: right;">Page 24</p> <p>1 relied upon the references that you see enumerated. 2 Q. Did you review any other depositions, 3 exhibits, or documents that were produced in this case 4 other than what you've listed in paragraph nine? 5 A. On -- only as I mentioned earlier this 6 morning. 7 Q. Okay. And as I recall your testimony from 8 earlier this morning, it wasn't deposition testimony 9 or documents that were produced in the case; correct? 10 A. I don't know what you mean exactly by 11 "produced in the case," but I looked at a rough draft 12 of much of Dr. Holford's deposition. 13 Q. Yeah. But other than that, with respect to 14 materials and depositions, exhibits and things that 15 have been produced in this case, the sum total of what 16 you reviewed is set forth in paragraph nine of your 17 report; correct? 18 A. I think that's correct, yes. 19 Q. Okay. 20 A. I'm not aware of anything else which might 21 have been eligible for listing that I have not listed. 22 Q. Okay. 23 MR. GORDON: And -- and Jan, just so you're 24 clear, I don't -- the distinction may be unclear to 25 Dr. Borak, but the Ridgeview documents he reviewed</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Okay. So you knew of his name before you 2 met him on May 8th. 3 A. Yes. 4 Q. Okay. 5 MR. GORDON: Jan, sorry, I'm a little slow 6 on the draw. He -- he didn't know her, but I had an 7 associate with me named Micah Hines. 8 THE WITNESS: I apologize. 9 MS. CONLIN: No offense taken on this side. 10 THE WITNESS: Thank you. 11 Q. So if we can take a look at your report, and 12 I'd like to direct your attention to page two of Borak 13 Exhibit No. 1, paragraph nine -- 14 A. Yes. 15 Q. Okay. In addition to the reference list, 16 which is contained on pages 24 through 27 of Exhibit 17 1, your June 2nd report, is this all of the material 18 that you reviewed? In other words, if I take 19 paragraph nine and I take your reference list, which 20 is contained on pages 24 through 27, is that the sum 21 total of the materials that you reviewed in connection 22 with your opinions in this case? 23 A. No. 24 Q. Okay. What else did you review? 25 A. I reviewed a great amount of literature. I</p>	<p style="text-align: right;">Page 25</p> <p>1 were documents produced by Ridgeview -- 2 MS. CONLIN: Okay. 3 MR. GORDON: -- pursuant to subpoena, not 4 pursuant to a deposition. 5 MS. CONLIN: Understood. 6 Q. Let me ask it a different way. Prior to the 7 time you rendered your opinions in this case on June 8 2nd, 2017, does paragraph nine in your report set 9 forth everything that you reviewed by way of 10 depositions, transcripts, exhibits and documents 11 produced in the case? 12 A. Yes, I think that is correct. 13 Q. Now how did you go about deciding what you 14 were going to review as reflected in paragraph nine? 15 A. I think most of these were sent to me by Mr. 16 Gordon's office. 17 Q. Okay. So the documents and transcripts 18 reflected in paragraph nine of your report were 19 selected for you and sent to you by Mr. Gordon; 20 correct? 21 A. They were sent to me by Mr. Gordon. 22 Q. Okay. Did you ask him for them, or did they 23 just arrive? 24 A. It was probably some conversation by phone 25 related to the fact that there were documents and they</p>

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<p style="text-align: right;">Page 26</p> <p>1 would be sent. I think the one that I requested or 2 that came as a consequence of a request was the 3 deposition of Dr. Nachtsheim -- 4 Q. Yeah, Nachtsheim. Yeah. 5 A. N-a-c-h-t-s-h-t-e-i-m. 6 -- and that was a response to a statement 7 that was in Dr. Samet's report. I believe, if I 8 recall, Dr. Samet referred to an extended series of 9 cases or something of that sort -- I could look it up, 10 but I think you understand what I'm speaking to -- and 11 I said, "What is that?" And I was sent this add -- 12 added material because I didn't understand that 13 statement from this Samet report. 14 Q. Okay. When were you retained in this case? 15 A. Probably in late April, but I don't remember 16 specifically. 17 Q. So the first time you were retained in this 18 case was in late April after Dr. Samet had issued his 19 report. 20 A. I -- I'm not sure of the chronology 21 specifically. 22 Mr. Gordon was somebody I have known for 23 some years. We had spoken of this. And I was not 24 retained or participating, and he was speaking to me 25 as a colleague friend, and one day he said, "I would</p>	<p style="text-align: right;">Page 28</p> <p>1 identified a series of search strings. I might very 2 well have searched on the word -- or phrase "Bair 3 Hugger." I would have looked at literature on 4 orthopedic infections. In addition, from time to time 5 Mr. Gordon would send me articles, some of which might 6 have been more obscure than not. Some of them were 7 from some fairly-out-of-the-way English journals, and 8 for some of these I actually had to register with the 9 journals to be able to access their articles, and I 10 did so. 11 Q. Do you have a record of what searches you 12 performed or do you have the documents that you 13 pulled, the articles, -- 14 A. The answer -- 15 Q. -- in your office? 16 A. The answer to the first one is probably not, 17 but the answer to the second one is yes. 18 MS. CONLIN: Okay. We're going to ask for a 19 full list of all the publications that he pulled and 20 reviewed in connection with his opinions in this case. 21 Q. Would you agree with me -- I think you did, 22 so I apologize for asking again -- but as a -- 23 When you're investigating an issue with your 24 epidemiologist's hat on, it's important to have all 25 the information in order to make your decision or</p>
<p style="text-align: right;">Page 27</p> <p>1 like to get you involved in this," and that day we 2 went from being friends to being client and 3 consultant. 4 Q. And that was sometime in late April? 5 A. I think so. 6 Q. How did you go about compiling the -- you 7 said -- 8 In paragraph 10 you said, "I also reviewed a 9 large number of scientific reports related to surgical 10 warming devices, operating room procedures, surgical 11 complications and infections, and other related 12 medical and scientific issues." How did you go about 13 gathering that information? 14 A. I'm trying to reconstruct the history as 15 clearly as I can. I -- I assume -- I'm not certain 16 but I assume that initially, after discussions with 17 Mr. Gordon, I was provided a packet of materials and 18 told that this was background materials, and that 19 probably would have included the studies from 20 Northumbria and that sort of thing. And I have in my 21 office a full-time librarian who does routinely 22 extensive literature searches for me using the Yale 23 library and the National Library of Medicine, and we 24 pick keywords and we search on things, and so sometime 25 after I had read those first papers I would have</p>	<p style="text-align: right;">Page 29</p> <p>1 opinion; correct? 2 MR. GORDON: Object to the form of the 3 question. 4 A. I -- I would say that generalizes to many 5 fields, yes. 6 Q. Okay. And did you ever ask the lawyers for 7 3M for any of the other deposition transcripts or 8 documents that have been produced in this case? 9 A. I -- I -- I'm not aware that I asked for 10 them. 11 Q. Okay. Did you ask for any information 12 relating to the Bair Hugger, how it's constructed or 13 how it operates? 14 A. I believe I did, and I believe I received 15 some information, and I believe I made the point that 16 I was not a mechanical engineer and that I was not a 17 ventilation expert, that I was not a filtration 18 expert, and that I was not going to render an opinion 19 that relied upon such possible expertise. 20 Q. What materials did you receive related to 21 the Bair Hugger that aren't listed in exhibit nine? 22 A. I -- I can't recall what I've read. I mean 23 I've read certainly in depositions and in some of the 24 exhibits to some of the depositions, but I don't 25 specifically recall because it was not a field that I</p>

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<p style="text-align: right;">Page 30</p> <p>1 was looking at specifically. 2 Q. Well don't you think it's important, if 3 you're trying to ascertain whether use of the Bair 4 Hugger increases a risk of an infection, that you 5 understand how it operates? 6 MR. GORDON: Object to the form of the 7 question. 8 A. I thought that the relevant question was 9 whether the Bair Hugger was associated with infection, 10 and so I really focused on the issue of whether there 11 were infections. 12 Q. But in connection with looking at whether 13 it's associated with infections, you didn't think it 14 was important to understand how the device operates? 15 A. I thought I understood enough in principle 16 in how it operated, but I was not going to be opining 17 upon whether, for example, the motor was too large or 18 too small, or whether the filters were too large or 19 too small, or -- and -- and so forth, that I was not 20 going to be rendering that kind of an opinion and that 21 that was not my area of expertise. 22 Q. Well if -- if you don't know how the machine 23 operates, take into account, for example, the filter 24 or the -- the efficiency of the filter, how is it that 25 you can opine that there is absolutely no association</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. What do you mean "linked to Dr. Augustine?" 2 Setting aside the new Augustine publication, 3 which is self-evident, explain what you mean. 4 You're -- you're referencing Augustine and 5 McGovern; correct? 6 A. Correct. 7 Q. Okay. 8 A. Well my understanding is that the McGovern 9 paper was largely if not entirely funded by Dr. 10 Augustine, and that the analyses were performed by a 11 member of his staff. 12 Q. Do you think that funding of a study by a 13 particular party undercuts its scientific validity? 14 A. It does not necessarily undercut its 15 scientific validity. 16 Q. Okay. So why were you referencing that the 17 McGovern study in your mind was funded by Augustine? 18 A. I -- I said they were associated with Dr. 19 Augustine and you asked me to clarify what I meant by 20 "associated," and I tried to explain that. 21 Q. Why did you think that was important, to 22 suggest that these two studies had some involvement by 23 Augustine? 24 A. I -- 25 Q. And by the way, I'm not accepting your</p>
<p style="text-align: right;">Page 31</p> <p>1 between the Bair Hugger and a risk of infection? 2 MR. GORDON: Object to the form of the 3 question, also misstates his testimony. 4 A. Yeah. I haven't said that there was 5 absolutely no association. I said I've seen no 6 evidence of any association; that was, other than two 7 troubled studies. 8 Q. Okay. So that's why you've opined there is 9 no association between the Bair Hugger and a risk of 10 infection. 11 A. I have opined that I have seen no evidence 12 that there is an association, except for two troubled 13 studies. 14 Q. Right. And my point is is without 15 understanding how the machine operates, is -- 16 Is it just these two studies and that's what 17 you did, and you found those studies to have issues so 18 your conclusion is based on that? 19 A. I -- I have looked at the literature and 20 found no evidence of infections associated with use of 21 the Bair Hugger, which I understand to be a very- 22 large-volume-used instrument, and the only evidence 23 which I have seen to suggest that it causes infection 24 are the two papers that have been linked to Dr. 25 Augustine.</p>	<p style="text-align: right;">Page 33</p> <p>1 premise, but why -- why did you think that was 2 important? 3 A. I -- I simply used that to describe. But I 4 can take back the description. The description is 5 unimportant. The point I was making is that to the 6 best of my knowledge, having looked at a lot of the 7 literature, the only two studies that have proposed an 8 association between the use of the Bair Hugger and 9 infection are the McGovern and the Augustine papers. 10 Q. Okay. You would agree with me that funding 11 of a particular study does not suggest on its face 12 that there's a problem with it; correct? 13 A. It always raises suggestions. I deal with 14 that every time that I have worked for a funding 15 source that might have been regarded as a source of 16 conflict of interest. It's one of the things I'm 17 constantly aware of in my own work, and I'm aware of 18 it in others', and I'm aware of it when I sit on an 19 editorial board and peer review other people's 20 submissions. 21 Q. And your position is that as a scientist, 22 you're -- you're for hire but your opinions are not 23 for hire; correct? 24 A. There's something vulgar about the way you 25 say it, but the fact of the matter is that my opinions</p>

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<p style="text-align: right;">Page 34</p> <p>1 are not for sale, only my time.</p> <p>2 Q. Okay. And you would expect that to be the</p> <p>3 case for any legitimate doctor or scientist that's</p> <p>4 investigating an issue; correct?</p> <p>5 A. One would hope.</p> <p>6 Q. Okay.</p> <p>7 (Discussion off the stenographic record.)</p> <p>8 BY MS. CONLIN:</p> <p>9 Q. I have handed you, sir, what's been marked</p> <p>10 previously as Holford Deposition Exhibit 13, which is</p> <p>11 the McGovern paper that we've been discussing;</p> <p>12 correct?</p> <p>13 A. Correct.</p> <p>14 Q. Do you know any of the authors on this</p> <p>15 paper?</p> <p>16 A. I have read a lot of their work, but I never</p> <p>17 met any.</p> <p>18 Q. Okay. Did you --</p> <p>19 Do you know who Dr. Belani is, for example?</p> <p>20 A. I would be unable to describe him.</p> <p>21 Q. Okay. Do you know where he works?</p> <p>22 A. I could look it up, but I don't.</p> <p>23 Q. Okay. How about Drs. McGovern or Reed?</p> <p>24 A. Well I'm familiar with Dr. McGovern and Reed</p> <p>25 as part of the Northumberland Health Trust. But Dr.</p>	<p style="text-align: right;">Page 36</p> <p>1 credentialed. I don't think that that is necessarily</p> <p>2 the assurance. It helps, but it does not assure.</p> <p>3 Q. Well which one of these McGothen --</p> <p>4 McGovern authors are you suggesting engaged in data</p> <p>5 manipulation?</p> <p>6 A. I -- I don't know which ones. I have their</p> <p>7 depositions. I've cited from their depositions. They</p> <p>8 agree, for example, that the published data differed</p> <p>9 from the final data.</p> <p>10 If I could look at my notes -- or not my</p> <p>11 notes, but my report, I have citations specifically to</p> <p>12 their depositions, and I was using their words.</p> <p>13 Q. Okay. My question is a little different, so</p> <p>14 try to answer mine. My question is: Which of these</p> <p>15 authors are you suggesting engaged in data</p> <p>16 manipulation?</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 A. I -- I -- I don't have information to tell</p> <p>20 me which ones did. I understand, from the sequence of</p> <p>21 deposition information, that Dr. Reed at some point in</p> <p>22 his deposition said, "It's clear to me that some of</p> <p>23 the data on the clinical side are wrong," that Mr.</p> <p>24 Albrecht says, "It looks like it didn't line up a</p> <p>25 hundred percent. I'm not sure what's going on," Dr.</p>
<p style="text-align: right;">Page 35</p> <p>1 Reed is a well known orthopedic surgeon. I think Dr.</p> <p>2 McGovern was probably a junior to Dr. Reed.</p> <p>3 Q. Okay. Was there a reason why you didn't</p> <p>4 read Dr. Belani's deposition?</p> <p>5 A. I frankly wasn't aware that there was a</p> <p>6 deposition of Dr. Belani.</p> <p>7 Q. Okay. Well one of the things that you</p> <p>8 suggest about the McGovern study is that there was</p> <p>9 potentially data manipulation; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 A. Potentially.</p> <p>13 Q. All right. When making that accusation,</p> <p>14 wouldn't it be important to look at the credentials of</p> <p>15 the people against whom you're making that accusation?</p> <p>16 A. Unfortunately, the credentials are not</p> <p>17 the -- the assurance of probity.</p> <p>18 Q. Well you'd have to look and see whether</p> <p>19 these were the type of individuals that would</p> <p>20 manipulate data; correct?</p> <p>21 MR. GORDON: Object to the form of the</p> <p>22 question, also lack of foundation.</p> <p>23 A. I have, as a member of an editorial board,</p> <p>24 been required to vote for the retraction of an article</p> <p>25 from authors who have been extraordinarily well</p>	<p style="text-align: right;">Page 37</p> <p>1 Reed and Albrecht said, "There are differences." And</p> <p>2 I don't know --</p> <p>3 You're asking me who is personally and</p> <p>4 individually responsible. I don't know the answer to</p> <p>5 that.</p> <p>6 Q. Okay. You --</p> <p>7 Did you read the whole depositions?</p> <p>8 A. I did at some point, yes, absolutely.</p> <p>9 Q. Okay. How did you decide the quotes that</p> <p>10 you put in your report? Were those ones that were</p> <p>11 suggested to you by 3M?</p> <p>12 A. No, absolutely not.</p> <p>13 Q. So they were ones you chose.</p> <p>14 A. Yes.</p> <p>15 Q. Well you know that Dr. Reed testified that</p> <p>16 "The data file for the paper was definitely correct.</p> <p>17 I checked it multiple times." Correct?</p> <p>18 A. I --</p> <p>19 He may have said that, but he also said that</p> <p>20 there were mistakes and that there was additional</p> <p>21 cases.</p> <p>22 Q. You're referring to his testimony that he</p> <p>23 thought maybe there was an additional infection in</p> <p>24 each group?</p> <p>25 A. I believe that's how he testified, correct.</p>

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<p style="text-align: right;">Page 38</p> <p>1 Q. Okay. And that was a deposition that was 2 taken, what, years after the publication; correct? 3 A. I guess so, but I don't know for sure. 4 Q. So how did you -- 5 If you think that one or more of these 6 authors engaged in data manipulation, how did you 7 decide what you were going to rely on from their 8 depositions and what you were going set aside as being 9 false? 10 A. I can't construct or reconstruct my thought 11 at the time that I read these things, but these 12 statements struck me as being supportive of the fact 13 that there were some differences in the data and that 14 the published data were not the final data. 15 Q. Did you do any investigation into the data 16 tabulation sets which have been marked as and referred 17 to as McGovern Exhibit 16 or Albrecht Exhibit 10? 18 A. I have -- I have looked at both. If I'm 19 correct, the Albrecht Exhibit 10 is a very, very thick 20 document, and I have leafed through it in part trying 21 to see if I could locate in there the individual who 22 was identified in the McGovern Exhibit 16 as case 23 number 44. If I'm correct, that one is a rather 24 small, much more concise document. But I have not 25 made any kind of definitive effort to review either of</p>	<p style="text-align: right;">Page 40</p> <p>1 spend as a consultant, under the umbrella of Jonathan 2 Borak & Company, versus teaching? 3 A. Probably 85 percent or more. 4 Q. Is through Jonathan Borak & Company? 5 A. That's correct. 6 Q. And of that 85 percent of your time, how 7 much is in consulting versus litigation? 8 A. I'm sorry. So the distinction you're saying 9 is consulting that is not litigation-based. 10 Q. Right. 11 A. Let -- let me step back. I -- 12 Just to be clear, many if not all of my 13 clients -- not all, but most of my clients are 14 lawyers. Often I am approached by lawyers to do non- 15 litigation work or work that is not directly relevant 16 to my being an expert in a litigation. For example, 17 we recently were involved in doing a vetting of a 18 company's website and documentation prior to an 19 acquisition. We did that for an attorney. I have 20 done work in the regulatory area and I'm almost always 21 approached by an attorney. But the answer is I think 22 that I have testified perhaps four or five times in 23 the past four years, and I do a variety of different 24 kinds of work. I would guess, because it's not 25 constant, but I would guess that about 30 percent or</p>
<p style="text-align: right;">Page 39</p> <p>1 those two documents. I understand that that has been 2 done by Dr. Holford, and I rely upon Dr. Holford's 3 ability to do that. 4 Q. Okay. So with respect to the veracity of 5 McGovern Exhibit 16 or Albrecht Exhibit 10 and what it 6 shows or doesn't show, you're relying on Professor 7 Holford on that. 8 A. In terms of the statistics and the matching 9 up of the case numbers and those sorts of things, yes, 10 I'm ultimately relying upon Dr. Holford. 11 (Exhibit 3 was marked for 12 identification.) 13 BY MS. CONLIN: 14 Q. I've handed you, sir, what's been marked as 15 Borak Deposition No. 3, which is a page off of your 16 company website; correct? 17 A. Correct. 18 Q. And this was founded in what, 1988? 19 A. That sounds right. 20 Q. Okay. 21 A. '86 I think. 22 Q. And how many people are employed at Jonathan 23 Borak & Company? 24 A. Currently there are four full time. 25 Q. Okay. And how much of your time do you</p>	<p style="text-align: right;">Page 41</p> <p>1 so of my income is litigation-related. 2 Q. Thirty percent of your income from the 3 Jonathan Borak & Company. 4 A. I would guess, yes. 5 Q. Okay. 6 A. And yes, I think that's correct. 7 Q. Okay. Now you indicate here that you serve 8 mainly to Fortune 500 companies and their 9 representatives, government agencies, national labor 10 unions, and professional societies; is that fair? 11 A. I think so. 12 Q. Okay. In the past two decades, to the 13 extent that you've done work in litigation, -- 14 A. Yes. 15 Q. -- it's been for the defense; correct? 16 A. What time period was that? 17 Q. Last two decades. 18 A. At one time I did a lot of plaintiffs' work. 19 Over the recent past it has been predominantly 20 defense, but I do some lit -- plaintiffs' side. 21 Q. Okay. In the last decade, have you done a 22 single case on the plaintiffs' side? 23 A. I have not testified on the plaintiffs' 24 side, but I have done plaintiffs'-side work. 25 Q. What types of cases?</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. Water contamination by perfluorooctanoic 2 acid. 3 Q. Anything else? 4 A. That was the largest one recently. There 5 have been others. Sometimes it's not clear to me who 6 is a plaintiff or a defendant. I know that sounds 7 peculiar. But I was involved in a very large 8 situation of a company that had acquired a division 9 from another company that made respirators, and as 10 part of the acquisition the seller retained certain 11 historical liabilities and the acquirers accepted 12 other liabilities, and it became a question of whether 13 coal miners' pneumoconiosis could develop in the 14 absence of silica. There was no question of damages 15 to individuals in the sense that it was not a question 16 of whether somebody was or was not going to get 17 compensation, it was a question of which insurance 18 pool was going to pay for it. That -- that is 19 something where it's a litigation-based piece of work, 20 but I don't see it as being plaintiff and defense as 21 you raised the question. 22 Q. Yes. It was an issue of retained 23 liabilities versus assumed liabilities. 24 A. In that particular case. 25 Q. And in that case --</p>	<p style="text-align: right;">Page 44</p> <p>1 adjudication of responsibility. 2 Q. My question was a little different. When 3 you've opined on causation in the litigation context, 4 there hasn't been a single time where you have found 5 that an environmental toxin caused harm in an 6 individual. 7 MR. GORDON: Object to the form of the 8 question, also asked and answered. 9 A. Yeah. I'm -- I'm not sure that I can 10 remember -- 11 I mean it may -- it may be that when I 12 render such an opinion, people decide to settle their 13 cases. I don't know. 14 Q. Can you -- 15 As you sit here today, can you think of a 16 single instance in the last two decades where in the 17 litigation context you have opined that exposure to a 18 particular environmental toxin or otherwise caused 19 harm in an individual? 20 A. I -- I can't remember a specific example of 21 the other side either, so perhaps you can help me. 22 Q. Okay. Well we'll go through them. But as 23 you sit here, can you name one? 24 A. I don't know that I can name one to the 25 other side. Most of what I have done has involved --</p>
<p style="text-align: right;">Page 43</p> <p>1 A. I have done a number of such pieces of work. 2 Q. And the issue was whether there was 3 causation presented by the silica. 4 A. Whether silica was sufficient a causation 5 that it belonged in one pot rather than in the other 6 pot, yes. 7 Q. Okay. Have you ever in litigation, just 8 putting on your litigation hat, opined that exposure 9 to an environmental toxin caused harm? 10 A. In a litigation context. 11 I've certainly written that it can. I don't 12 know that I have in a specific litigation context. 13 Q. In fact, in the litigation context every 14 single one of your retentions resulted in you opining 15 that whatever the exposure to an environmental toxin 16 was didn't cause the harm alleged by the injured 17 person; correct? 18 A. I -- I think that you misrepresent my 19 opinions. I've been in a number which have to do with 20 concerns about what was known and when was it known 21 and whether a particular entity was responsible, and I 22 don't think any of those opinions suggested that the 23 claimants were uninjured. There may have been some 24 cases where I have said that, but I think that many of 25 my opinions have dealt with questions of the</p>	<p style="text-align: right;">Page 45</p> <p>1 Well let me go back. With the exception 2 of -- 3 Where I have testified. 4 Q. Not where you've testified, where you've 5 rendered an expert opinion in a case, whether it be 6 through trial, deposition, or a report -- 7 A. Well I think a deposition -- 8 Okay. Report. I -- I've written reports 9 and I have never known whatever happened to those 10 things. In some cases I felt that there was -- 11 Oftentimes, people ask me not to write 12 reports when I don't agree with their view, so when 13 defense lawyers ask me whether I think A causes B and 14 I say yes, they say thank you, and it never progresses 15 beyond that. 16 Q. Can you answer my question? 17 A. What is your question? 18 Q. My question is: As you sit here today, can 19 you identify a single instance in which you've 20 rendered an expert opinion in litigation that exposure 21 to an environmental toxin caused harm in an 22 individual? 23 MR. GORDON: Object to the form of the 24 question, asked and answered. 25 A. Most recently I have spent a fair amount of</p>

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<p style="text-align: right;">Page 46</p> <p>1 time looking at these perfluorooctanoic acid exposures 2 and I have offered verbal reports but I have not 3 written reports, and the reports were that there was 4 causation. 5 Q. Okay. Can you answer my question though? 6 In terms of -- 7 A. I -- I cannot remember is the answer. 8 Q. Okay. When did you become a consultant to 9 the National Mining Association? 10 A. I don't remember the date. 11 Q. Okay. 12 MR. GORDON: Let me interrupt. I'm -- 13 I'm -- I'm -- 14 The section where he discusses his -- 15 whatever he did with PFOA, I have no idea where that 16 is in the litigation process, I'm not involved in it, 17 but I -- it sounds to me like something that probably 18 ought to be marked as confidential. 19 MS. CONLIN: I don't have an issue with 20 that. 21 Q. You authored a study that was funded by the 22 National Mining Association; correct? 23 A. Remind me of the title. 24 Q. Sure. 25 (Exhibit 4 was marked for</p>	<p style="text-align: right;">Page 48</p> <p>1 is also likely to be geographically associated with a 2 variety of adverse health outcomes. Although our 3 results indicate that mining is not the direct cause 4 of those outcomes, they do not rule out the 5 possibility that mining contributes to the development 6 of the social environments and cultural practices that 7 adversely impact health." 8 Q. Right. 9 A. My belief was and is that it is not 10 pollution from the coal mines but social pollution 11 from the industry that has caused these disparities. 12 Q. Right. That there is no direct link between 13 coal mining and adverse health outcomes. 14 A. No, no. I think that the coal mining 15 industry and its social context has contributed to 16 these adverse effects. 17 Q. Well let's take a look at the last page -- 18 well, second-to-the-last page. I think it's got an 19 internal number 154. Direct your attention to the 20 right-hand side, first full paragraph starting with 21 "Accordingly..." and direct your attention down to the 22 sentence, "Although our results indicate that mining 23 is not the direct cause of those outcomes, they do not 24 rule out the possibility that mining contributes to 25 the development of social environments and cultural</p>
<p style="text-align: right;">Page 47</p> <p>1 identification.) 2 BY MS. CONLIN: 3 Q. I've handed you, sir, what's been marked as 4 Borak Deposition Exhibit No. 4, which is an article 5 authored by you and others entitled "Mortality 6 Disparities in Appalachia." 7 A. Yes. 8 Q. Okay. And this was a study that you 9 authored that was funded entirely by the National 10 Mining Association; correct? 11 A. Yes, that's correct. 12 Q. And you wouldn't suggest that because the 13 National Mining Association funded this study, that 14 that somehow taints this; correct? 15 A. No. They were unhappy with it. 16 Q. Okay. And in this you conclude that there 17 hasn't been any solid epidemiological evidence that 18 coal mining increased risks to population health in 19 the Appalachia region; correct? 20 A. I think you misspeak it. I -- I think that 21 what we found was "...that coal mining in Appalachia, 22 an industrial activity associated with rural, 23 mountainous areas, is likely to be geographically 24 associated with a variety of economic and cultural 25 health risk factors. And, for similar reasons, mining</p>	<p style="text-align: right;">Page 49</p> <p>1 practices that adversely impact health." 2 A. That's the sentence I just read to you. 3 Q. Okay. And you find that mining is not a 4 direct cause of the -- and it's your word, "direct 5 cause" -- of the health -- strike that. 6 Let me say you find that mining itself is 7 not a direct cause of illness in a population; 8 correct? 9 A. Yes, that it was the -- the mining 10 industry's influence on the social environment. 11 Q. Right. People are getting black lung 12 disease because they're overweight and poor. 13 A. The people who were suffering health 14 disparities in this community were not miners and they 15 were not getting black lung. 16 Now in fact we make mention here that it is 17 not because of the miners that there were these health 18 disparities and that the disparities existed in both 19 males and females, although the females did not work 20 in the mines. Black lung is a disease of occupation. 21 That's not the issue of concern in this paper. 22 Q. Well you were actually interviewed a bunch 23 in connection with this article; weren't you? It 24 caused quite a stir; correct? 25 A. I don't know that it caused quite a stir,</p>

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<p style="text-align: right;">Page 50</p> <p>1 but I think I had a couple of interviews. 2 Q. And you said the health effects due to coal 3 and coal mining is just not known; correct? 4 A. I'm sorry? 5 Q. You -- you were quoted as saying the health 6 effects due to coal and coal mining is just not known; 7 correct? 8 A. Regarding people in the community. 9 Q. And in fact you said, quote, "The problem is 10 that the theory that this is due to coal and coal 11 pollution is politically attractive but scientifically 12 not defensible;" correct? 13 A. That sounds like something I would have 14 said. 15 Q. Okay. And you said, quote, "It may or may 16 not be due to coal mining, I actually don't know, but 17 I think it could be, but it's not due to the coal;" 18 correct? 19 A. That sounds right. 20 Q. Okay. And you said while the work was 21 funded by the National Mining Association, quote, your 22 time is for hire, your opinions are not. 23 A. Okay. That sounds like something I said to 24 you earlier today. 25 Q. You were also caught up in some controversy</p>	<p style="text-align: right;">Page 52</p> <p>1 Do you say -- how do you say it, A-C-O-E-M? 2 A. Or ACOEM if you -- 3 Q. ACOEM. Okay. 4 And you knew before it was published that 5 the authors were experts for the defense in mold 6 litigation; correct? 7 A. No. To the contrary, Dr. Hardin told me he 8 was not specifically. 9 Q. Okay. But e-mails came to light after that 10 publication which suggested that you did know before 11 publication. 12 A. Would you read that to me? I'm not aware 13 that I was aware that Dr. Hardin had been an expert. 14 To the contrary. 15 Q. Okay. 16 A. It also might be useful for the record to 17 note the date that this was: it's about like 15 years 18 ago. 19 Q. Yeah. It was in 2002; right? 20 A. Fifteen years ago. 21 Q. Yeah. Did you think that there was anything 22 that was -- undercut it -- undercut the validity of 23 that study because the authors were associated with 24 the defense? 25 A. Dr. Hardin specifically told me that he was</p>
<p style="text-align: right;">Page 51</p> <p>1 over a study involving mold; correct? 2 MR. GORDON: Object to the form of the 3 question. 4 A. There was controversy about a position paper 5 that was written by The American College of 6 Occupational Envi -- that was posted by The American 7 College of Occupational Environmental Medicine. I was 8 the chairman of the committee that oversaw the 9 development of the paper. I didn't write it and I had 10 little other than the fact that I kept the editorial 11 process going. 12 Q. All right. And that paper found that there 13 are no adverse health effects associated with toxic 14 mold; correct? 15 A. No, that's not what it found. 16 Q. What's your understanding of what it found? 17 A. What it found was that mold could cause a 18 number of allergic and irritative disorders, but that 19 which became known as, quote, unquote, toxic mold 20 syndrome was not; it had not been documented. It was 21 written by a former deputy director of The National 22 Institute of Occupational Safety and Health. I didn't 23 write it. 24 Q. Correct. But you -- you reviewed it as part 25 of your role as director on -- at --</p>	<p style="text-align: right;">Page 53</p> <p>1 not, and he gave me a statement of conflict of 2 interest, and I shared that with the board of ACOEM at 3 the time. 4 Q. My question was a little different. Did -- 5 did you think, when you found out that they 6 represented the defense in that litigation, that that 7 somehow impugned the veracity of the findings in that 8 paper? 9 A. When you say "that litigation," I am not 10 sure which litigation you speak to. I understood that 11 subsequently Dr. Hardin and his colleagues did opine 12 in litigation for the defense. 13 Q. Okay. And do you think, that they did that, 14 that undercuts at all the scientific veracity of the 15 paper you reviewed? 16 A. I thought the paper was fair. And it was 17 sent to a large, large, large number of peer 18 reviewers. I did not make the decision as to publish 19 or not. 20 Q. My question is: Do you think the fact that 21 they represented the defense undercuts at all the 22 scientific veracity of the paper? 23 A. No. 24 MR. GORDON: Could we take a potty break 25 fairly soon?</p>

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<p style="text-align: right;">Page 54</p> <p>1 MS. CONLIN: Yeah. We can stop here if 2 you'd like. 3 THE REPORTER: Off the record, please. 4 (Recess taken.) 5 (Exhibit 5 was marked for 6 identification.) 7 THE WITNESS: Thank you. 8 BY MS. CONLIN: 9 Q. I've handed you, sir, what's been marked as 10 Borak Exhibit No. 5, and this is the e-mail that we 11 were talking about just before the break as it relates 12 to your role at ACOEM and the publication of an 13 article by Dean Grove; is that right? 14 A. Yes. He was then president of the college. 15 Q. Okay. And this related -- 16 This is dated September 6th, 2002, and this 17 relates to the review by ACOEM of the article -- or 18 the study that was going to be published on whether -- 19 A. It was not a study, it was a review. 20 Q. -- whether a review was going to be 21 published; correct? 22 A. That's correct. 23 Q. Okay. And in this e-mail you indicated that 24 "Even though a great deal of work has gone in, it 25 seems difficult to satisfy a sufficient spectrum of</p>	<p style="text-align: right;">Page 56</p> <p>1 It sounds right, but show me where the word 2 "garbage" is. I'm sorry. 3 Q. If you look at the last full sentence in the 4 second paragraph, "That would be an important 5 violation" -- 6 A. Yes. Okay. Fine. I do see it. I just 7 want to make sure I used that word. 8 Q. You write, "That would be an important 9 violation of Bryan -- I have assured him that if we 10 do not use it he can freely make whatever other use he 11 might want to make. If we 'officially' reject it, 12 then we turn his efforts into garbage." Correct? 13 A. Correct. 14 Q. And that was the concern, that if the paper 15 didn't get published and was rejected by the college, 16 then the paper might not gain traction. 17 A. No, that was not the concern. 18 Q. What was your concern? 19 A. My concern was that Bryan was a very 20 respected scientist. I knew that he had interest in 21 mold because I had seen some of his writings. At that 22 time he was not, as I understood it, involved in the 23 issue other than as a scientific issue. I asked him 24 whether he would be willing to prepare this review for 25 purposes of the college and he agreed to do that. He</p>
<p style="text-align: right;">Page 55</p> <p>1 the College, or at least those concerned enough to 2 voice their views;" correct? 3 A. I'm sorry, say that again. 4 Q. There was concerns about the college about 5 publishing this review; correct? 6 A. I was concerned that this particular review 7 was polarizing the college members. 8 Q. Right. And you write here though, "Even 9 though a great deal of work has gone in, it seems 10 difficult to satisfy a sufficient spectrum of the 11 College, or at least those concerned enough to voice 12 their views." 13 A. Correct. 14 Q. Okay. And then you go on in the next 15 paragraph to suggest that if you officially reject it, 16 then you turn Mr. Grove's efforts into garbage; 17 correct? 18 A. No, this mis -- 19 Q. Or to -- 20 A. It was Dr. -- 21 It was Bryan, Dr. Hardin's efforts. 22 Q. Okay. So you were concerned if the college 23 rejected it, Dr. Hardin's efforts would be turned into 24 garbage; correct? 25 A. I --</p>	<p style="text-align: right;">Page 57</p> <p>1 spent quite a while putting a paper together. He sent 2 it to me. I sent it out to my panel of reviewers; 3 there may have been 20 or 30 or more people in the 4 college who reviewed it. They gave me back feedback. 5 And I returned it to Dr. Hardin and I said this is 6 what people think, it's too polarized, it's too this, 7 it's too that, it's not enough this, it's not enough 8 of that, "Are you prepared to change it?" And he said 9 "Yes." And so he then spent quite a bit of time 10 rewriting, and not different than what happens when I 11 sit on a journal review and somebody sends a paper in 12 and it goes back with comments from the reviewers 13 which says "Major revision required." And so the 14 major revision was done and it was sent back. And I 15 returned that to the reviewers and they sent back 16 comments to me. And I sent those comments back to 17 Bryan and I said, "It's better, but it's still not 18 sufficient for me to put it before the board of 19 directors because it's too polarizing, and I would 20 like you to address that these are the issues that 21 people are raising." And he revised it again and he 22 sent it back to me. And I sent it out to reviewers 23 and I said, "Does this answer your concerns?" And 24 there were people who came back with continuing 25 concerns. And so then I had the following problem,</p>

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<p style="text-align: right;">Page 58</p> <p>1 and that's what is described here.</p> <p>2 Q. When did you find out that he was an expert</p> <p>3 for the defense in mold litigation?</p> <p>4 A. After publication.</p> <p>5 Q. Did you ever go back and make the</p> <p>6 correction?</p> <p>7 A. That he was a post-hoc expert?</p> <p>8 Q. Yes.</p> <p>9 A. No.</p> <p>10 And so what then happened was --</p> <p>11 Q. I didn't ask you what happened next.</p> <p>12 A. You had asked --</p> <p>13 I was answering the earlier question. You</p> <p>14 don't want it?</p> <p>15 Q. No. I -- I don't think your answer was</p> <p>16 responsive to my question, so we'll move on.</p> <p>17 You've -- you've been a faculty member for</p> <p>18 the defense bar at various toxic tort seminars;</p> <p>19 correct?</p> <p>20 A. Once. I think once.</p> <p>21 Q. Just once?</p> <p>22 A. I gave a talk in March, I think, of this</p> <p>23 year on the peer-review process in science at a</p> <p>24 meeting of an organization that I had not heard of</p> <p>25 before, but it was the defense bar, and I gave that</p>	<p style="text-align: right;">Page 60</p> <p>1 that describes associations between environmental</p> <p>2 factors and health effects?</p> <p>3 A. Yes, they can.</p> <p>4 Q. You've opined that there is no causal</p> <p>5 connection between benzene and multiple myeloma; is</p> <p>6 that right?</p> <p>7 A. Yes, I opined on that.</p> <p>8 Q. Okay. And --</p> <p>9 A. I think in that case I opined --</p> <p>10 Q. I didn't ask --</p> <p>11 I just wanted to know whether you did or</p> <p>12 not.</p> <p>13 MR. GORDON: Well Jan, I think you ought to</p> <p>14 let him finish his answer.</p> <p>15 MS. CONLIN: I've asked him simply "yes" or</p> <p>16 "no" questions. I'm not going to waste my seven hours</p> <p>17 with him giving me speaking testimony in questions I</p> <p>18 didn't ask. You can -- you can ask him on followup.</p> <p>19 MR. GORDON: Yeah. But it may be a "yes" --</p> <p>20 what you think is a simple "yes" or "no" question, but</p> <p>21 you -- you don't get to decide that.</p> <p>22 Q. And more recently you've opined that there</p> <p>23 is no specific causation relating to CS teargas or</p> <p>24 causation relating to cleaning chemicals; correct?</p> <p>25 A. That was a very specific case, and in that</p>
<p style="text-align: right;">Page 59</p> <p>1 talk. I was invited -- I don't even remember who</p> <p>2 invited me, but I was with the Dean of Hastings Law</p> <p>3 School.</p> <p>4 Q. I didn't ask you about any of this.</p> <p>5 A. Okay.</p> <p>6 Q. My question was a simple one. You were a</p> <p>7 faculty member at BRI, which is a defense bar, in a</p> <p>8 toxic tort seminar; correct?</p> <p>9 A. Yes. I spoke about peer review in the</p> <p>10 scientific process, I think in March of this year.</p> <p>11 Q. Okay. And that's the only time that you</p> <p>12 think you've done that?</p> <p>13 A. I'm not aware of having done it other --</p> <p>14 It's possible, but I certainly don't</p> <p>15 remember it. And it wasn't recent.</p> <p>16 Q. Okay. Do you agree with me that the</p> <p>17 Bradford-Hill criteria is an appropriate methodology</p> <p>18 for addressing an epidemiological issue?</p> <p>19 MR. GORDON: Object to the form of the</p> <p>20 question.</p> <p>21 A. It's been adopted as a methodology. It's</p> <p>22 not really a methodol -- a methodology, it's a set of</p> <p>23 viewpoints.</p> <p>24 Q. Okay. Would you agree with me that</p> <p>25 observational epidemiological studies can yield data</p>	<p style="text-align: right;">Page 61</p> <p>1 case I said that there was no evidence that the</p> <p>2 exposure to the cleaning agents caused the complaints</p> <p>3 of the person who was the claimant, but that the CS</p> <p>4 teargas clearly was the cause of symptoms.</p> <p>5 Q. Did --</p> <p>6 If we can take a look at your expert report,</p> <p>7 and I'd like to talk with you a little bit about -- I</p> <p>8 think it's on page --</p> <p>9 You listed in your report the four times</p> <p>10 that you have testified in the last few years, and for</p> <p>11 some reason I cannot seem to find that in what I've</p> <p>12 got.</p> <p>13 A. I think it was in an addendum. I don't</p> <p>14 think I listed it specifically --</p> <p>15 Q. Well let's see if I can --</p> <p>16 A. -- in the report.</p> <p>17 Q. Let's see if I can find it.</p> <p>18 Here, I got it.</p> <p>19 (Exhibit 6 was marked for</p> <p>20 identification.)</p> <p>21 BY MS. CONLIN:</p> <p>22 Q. I've handed you, sir, what's been marked as</p> <p>23 Borak Exhibit 6. Is this a list of your deposition</p> <p>24 and trial testimony between January 1st, 2013 and June</p> <p>25 1st, 2017?</p>

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<p style="text-align: right;">Page 62</p> <p>1 A. Yes, that's correct.</p> <p>2 Q. Aside from this deposition today, have you</p> <p>3 had your deposition taken in any other litigation</p> <p>4 between June 1st of this year and today?</p> <p>5 A. I -- I had a deposition taken on, I think,</p> <p>6 June 9.</p> <p>7 Q. Okay. What was the name of that case?</p> <p>8 A. I think the caption was Oules, O-u-l-e-s, v</p> <p>9 Johnson & Johnson.</p> <p>10 Q. And what was the subject matter of your</p> <p>11 testimony in that case?</p> <p>12 A. The question I was asked to address was</p> <p>13 whether, when, and how it had been opined that talc</p> <p>14 caused ovarian cancer.</p> <p>15 Q. And you represent --</p> <p>16 Or your client in that case is Johnson &</p> <p>17 Johnson?</p> <p>18 A. No.</p> <p>19 Q. The plaintiff?</p> <p>20 A. It is -- was a trade organization.</p> <p>21 Q. And in that case did you opine that there is</p> <p>22 no causal connection between talc and ovarian cancer?</p> <p>23 A. I -- I testified that the causation had not</p> <p>24 been proven.</p> <p>25 Q. That there wasn't a proven causal link</p>	<p style="text-align: right;">Page 64</p> <p>1 person who was a consumer of popcorn, and the</p> <p>2 individual himself had a significant underlying</p> <p>3 rheumatological disease which was the likely cause of</p> <p>4 his lung disease.</p> <p>5 Q. You found that exposure to diacetyl didn't</p> <p>6 cause the problems in the plaintiff in that case;</p> <p>7 correct?</p> <p>8 A. No, no, I didn't. The -- the problem --</p> <p>9 Your original question was whether I had</p> <p>10 opined that diacetyl did not cause the bronchiolitis</p> <p>11 obliterans, and I said no, that's not correct, I was</p> <p>12 not asked that opinion. And it is actually my opinion</p> <p>13 that under some circumstances diacetyl can cause the</p> <p>14 bronchiolitis obliterans.</p> <p>15 Q. But it didn't in this particular plaintiff.</p> <p>16 A. In this particular case, I don't believe</p> <p>17 that it did.</p> <p>18 Q. Okay. And what about In Re: World Trade</p> <p>19 Center, what was the subject matter of your testimony</p> <p>20 in that?</p> <p>21 A. The subject matter had to do with lung</p> <p>22 disease in somebody who had been a cleanup worker in</p> <p>23 buildings in the periphery of the World Trade Center.</p> <p>24 Q. Okay. And in that case you found that the</p> <p>25 exposure by the worker didn't cause the disease;</p>
<p style="text-align: right;">Page 63</p> <p>1 between use of talc and ovarian cancer.</p> <p>2 A. I -- I wasn't asked that question. I was</p> <p>3 asked whether it had been opined and by whom and when,</p> <p>4 and I went through the literature, and I opined that</p> <p>5 it had not been said by anybody that it was a cause.</p> <p>6 Q. Were you --</p> <p>7 So your opinion was strictly that there</p> <p>8 was -- nothing in the literature provided a direct</p> <p>9 causal link between use of talc and ovarian cancer.</p> <p>10 A. I --</p> <p>11 You're paraphrasing what I said. I -- I</p> <p>12 said that a causal association had not been described</p> <p>13 in the literature and anywhere other than in court</p> <p>14 testimony.</p> <p>15 Q. Okay. Now in --</p> <p>16 You also testified in Stults versus American</p> <p>17 Popcorn Company in a deposition in 2013; correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And in that case you concluded that there is</p> <p>20 no causal link between diacetyl and what's known as</p> <p>21 popcorn lung; correct?</p> <p>22 A. No.</p> <p>23 Q. What was your testimony in that case?</p> <p>24 A. The testimony concerned the likelihood of a</p> <p>25 lung -- of bronchiolitis obliterans being caused in a</p>	<p style="text-align: right;">Page 65</p> <p>1 correct?</p> <p>2 A. It was my opinion that the man's cigarette</p> <p>3 smoking and long history that predated the World Trade</p> <p>4 Center explained his complaints.</p> <p>5 Q. Okay. And what was your -- subject matter</p> <p>6 of your testimony in Cabot Corporation?</p> <p>7 A. I -- I already alluded to that. That had to</p> <p>8 do with the adjudication in terms of the insurance</p> <p>9 coverage for -- between two companies.</p> <p>10 Q. And what was the particular chemical of</p> <p>11 concern?</p> <p>12 A. The issue had to do with if one could get</p> <p>13 coal miner's pneumoconiosis in the absence of silica.</p> <p>14 Q. And in that case you concluded that the --</p> <p>15 that he can't; correct?</p> <p>16 (Discussion off the stenographic record.)</p> <p>17 A. Yes. My conclusion was that the absence of</p> <p>18 silica, that -- no, let me turn it the other way --</p> <p>19 that the presence of silica contributed to the</p> <p>20 formation of pneumoconiosis.</p> <p>21 Q. Okay. And how about in the final case,</p> <p>22 Secretary of Labor (MSHA) versus Klondex Midas, which</p> <p>23 side were you on in this case?</p> <p>24 A. I -- I was involved with Klondex Midas, and</p> <p>25 the case concerned whether medical causes of loss of</p>

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<p style="text-align: right;">Page 66</p> <p>1 consciousness had been addressed and considered by a 2 coroner and others. 3 Q. And what did you opine in that case? 4 A. I agreed with statements from the coroner 5 that she had not looked for such causes and could not 6 render such an opinion. 7 Q. Now you talk in your expert report about 8 sufficient component causation; correct? 9 A. Yes. I think I spoke to it in the context 10 of Dr. Samet's report. 11 Q. Right. And you'd agree with me that it's a 12 well accepted methodology in epidemiological studies; 13 correct? 14 A. I accept the concept. 15 Q. Yeah. And in fact it was first espoused by 16 Dr. Rothman; correct? 17 A. I looked at it in Dr. Rothman's writings as 18 a result of Dr. Samet citing that, yes. 19 Q. And you'd agree with me Dr. Rothman is one 20 of the leading minds in epidemiology. 21 A. I think Dr. Rothman is a leading mind in 22 epidemiology. 23 Q. So you don't take issue with Dr. Samet's 24 methodology, just his conclusions; correct? 25 MR. GORDON: Object to the form of the</p>	<p style="text-align: right;">Page 68</p> <p>1 inferences after finding association requires 2 judgment? 3 A. Judgment is part of the requirements, yes. 4 Q. Okay. Would you agree with me that although 5 the drawing of causal inferences is informed by 6 scientific expertise, it is not a determination that 7 is made using an objective or algorithm -- algorithmic 8 methodology? 9 A. It is not necessarily. 10 Q. What do you mean by "it is not necessarily." 11 A. Well read me back your question and I'll 12 answer your second question. You asked me do I agree 13 that it is not, and I -- my answer was it was not 14 necessarily. 15 Q. Okay. Would you agree, quote, "Although the 16 drawing of a causal in" -- strike that. Let me start 17 over. 18 Would you agree with me, quote, "Although 19 the drawing of causal inferences is informed by 20 scientific expertise, it is not a determination that 21 is made using an objective or algorithmic 22 methodology," end quote? 23 A. Yes. It is not necessarily based upon such 24 an algorithmic approach. 25 Q. Would you agree with me that, quote,</p>
<p style="text-align: right;">Page 67</p> <p>1 question. 2 A. I -- I don't object to his use of the 3 sufficient component cause model. I raise concerns at 4 the end of this section of my report and we could 5 address that specifically. Now it's not only the 6 conclusion, there was something in the method that I 7 had a problem with. 8 Q. Okay. But the sufficient component 9 causation methodology is well established and accepted 10 amongst epidemiologists. 11 A. I -- I think probably. I -- I don't -- 12 I'm not objecting to that. 13 Q. Okay. And in fact you went through the same 14 framework in connection with responding to Dr. Samet's 15 report; correct? 16 A. Well I probably would have done that to be 17 responsive to Dr. Samet. I don't know if I would have 18 done it otherwise. 19 Q. Okay. But you did in fact use the same 20 framework. You didn't employ a different framework -- 21 A. No. No. 22 Q. -- in connection with responding; correct? 23 A. Yes, that's correct I think. 24 Q. Okay. Would you agree with me that when 25 you're looking at epidemiology, that drawing causal</p>	<p style="text-align: right;">Page 69</p> <p>1 "Deciding whether associations are causal is not a 2 matter of statistics but a matter of good scientific 3 judgment and the questions that should be asked with 4 respect to the data offered?" 5 A. In principle. But there are some terms in 6 that sentence which are difficult to define, such as 7 "good." "Good judgment" I think was the word. 8 Q. Good scientific judgment. 9 A. Good scientific judgment. I don't know 10 quite what that means. But I can understand the 11 sentence. 12 Q. Well would you agree with me that The 13 Reference Guide on Statistics authored by Drs. Kay and 14 Friedman is an authoritative work? 15 A. It's a reference that I refer to. 16 Q. Okay. And you rely on it; right? 17 A. I do. 18 Q. And you don't take issue with what Drs. Kay 19 and Friedman have written in connection with The 20 Reference Guide on Statistics. In fact, you've relied 21 on it; correct? 22 A. That's correct. 23 Q. I'd like to direct your attention, sir, to 24 paragraph -- or page three of your expert report in 25 this case, Borak Exhibit No. 1. Do you have that in</p>

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<p style="text-align: right;">Page 70</p> <p>1 front of you?</p> <p>2 A. I do.</p> <p>3 Q. Okay. And I'd like to direct your attention</p> <p>4 to Roman No. II, "The Samet Report." In 11a you talk</p> <p>5 about this notion that there is sufficient evidence</p> <p>6 that warming surgical patients to prevent hypothermia</p> <p>7 and maintain normothermia reduces the rates of SSI;</p> <p>8 correct?</p> <p>9 A. Correct.</p> <p>10 Q. And you cite to the CDC's guideline as one</p> <p>11 of your references; correct?</p> <p>12 A. Yes.</p> <p>13 Q. And the World Health Organization; correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Did you investigate what -- what</p> <p>16 information either the CDC or WHO had in connection</p> <p>17 with their suggestion and determination that warming</p> <p>18 is important?</p> <p>19 A. Well I -- I've read the documents and I've</p> <p>20 looked at some of the references. Is that an answer</p> <p>21 to your question?</p> <p>22 Q. Okay. And you say in the next paragraph,</p> <p>23 "In addition, published findings from two random</p> <p>24 control trials document that use of Bair Hugger to</p> <p>25 maintain intraoperative normothermia reduced the risk</p>	<p style="text-align: right;">Page 72</p> <p>1 remember in that context there were questions that</p> <p>2 arose regarding infections. But that would have been</p> <p>3 some time ago.</p> <p>4 Q. Well you were a participant. It was part</p> <p>5 of --</p> <p>6 I mean you were involved in that case as a</p> <p>7 result of your work; correct?</p> <p>8 A. No, no. I was an expert in that context.</p> <p>9 Q. When was that?</p> <p>10 A. Oh, it --</p> <p>11 There were more than one, and it would have</p> <p>12 been before 1990 because before -- in 1990 I</p> <p>13 essentially separated myself from my emergency</p> <p>14 practice, and during the time between 1980 and 1990,</p> <p>15 approximately, I was involved in a fairly large number</p> <p>16 of litigation questions, often only from the</p> <p>17 standpoint of looking at medical records and saying</p> <p>18 whether I thought there was or was not some kind of a</p> <p>19 problem, and in that context, some of those involved</p> <p>20 infectious diseases.</p> <p>21 Q. Have you ever been retained, litigation or</p> <p>22 non-litigation, to provide an epidemiological opinion</p> <p>23 that relates to an infectious organism?</p> <p>24 A. I did some work several years ago at the</p> <p>25 interface of epidemiology and occupational medicine</p>
<p style="text-align: right;">Page 71</p> <p>1 of SSI."</p> <p>2 A. Yes, I said that.</p> <p>3 Q. Okay. I take it that you think the CDC in</p> <p>4 terms of --</p> <p>5 You know, let me strike that and ask it a</p> <p>6 different way.</p> <p>7 You relied on the CDC guidelines here in</p> <p>8 connection with your report; correct?</p> <p>9 A. I -- I cited it, yes.</p> <p>10 Q. Okay. And you relied on it.</p> <p>11 A. Well I relied upon it as an example of a</p> <p>12 statement from a well-regarded organization, yes.</p> <p>13 Q. Okay. And you agree the CDC is well-</p> <p>14 regarded; correct?</p> <p>15 A. Generally, yes.</p> <p>16 Q. Okay. In connection with your work over the</p> <p>17 course of your career, your emphasis has been on</p> <p>18 exposure to environmental toxins as opposed to</p> <p>19 infectious agents; correct?</p> <p>20 A. For the most part.</p> <p>21 Q. Have you ever opined in a case that involved</p> <p>22 not an environmental toxin but an infectious agent?</p> <p>23 A. Years ago, when I ran a trauma center, I was</p> <p>24 involved in litigation that involved malpractice kinds</p> <p>25 of issues, clinical malpractice issues, and I can</p>	<p style="text-align: right;">Page 73</p> <p>1 and public health, and it was during the Ebola</p> <p>2 outbreak, and it had to do with the development of</p> <p>3 occupational protocols for workplaces to minimize the</p> <p>4 risk of spread of that infectious disease. The</p> <p>5 particular issue involved some companies that operated</p> <p>6 mines in the Caribbean who had workers, many of whom</p> <p>7 went back and forth to Africa at the time. I recall</p> <p>8 as well being involved in the development of</p> <p>9 influenza-related policies for workplaces,</p> <p>10 white-collar workplaces, at a time when either SARs or</p> <p>11 influenza was of great concern. So those are two</p> <p>12 examples.</p> <p>13 Q. Okay. My question was a little different.</p> <p>14 Have you ever undertaken an epidemiologic study that</p> <p>15 relates to looking at causation issues of an</p> <p>16 infectious organism?</p> <p>17 A. Oh, that's a different question. I think</p> <p>18 the answer is probably no.</p> <p>19 Q. Now if we look at the paragraph we were</p> <p>20 looking at, you say, "In addition, published findings</p> <p>21 from two random control trials document that use of</p> <p>22 Bair Hugger to maintain intraoperative normothermia</p> <p>23 reduced the risk of SSI," and you list references</p> <p>24 three and four. And if we look at your reference</p> <p>25 list, that refers to a paper by Kurz and Sessler as</p>

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<p style="text-align: right;">Page 74</p> <p>1 well as Melling; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. Okay. Did you look at the depositions that</p> <p>4 were taken by Dr. Kurz and Sessler in this case?</p> <p>5 A. I -- I don't think so. Let me --</p> <p>6 Dr. Kurz and Dr. Melling?</p> <p>7 Q. Well one paper was --</p> <p>8 A. You -- you asked me about --</p> <p>9 Q. -- Kurz and Sessler. My question was: Did</p> <p>10 you look at their depositions in this case?</p> <p>11 A. The answer is no, I don't believe so. I</p> <p>12 don't see them on my list.</p> <p>13 Q. Were you aware or told that Dr. Kurz</p> <p>14 disavowed both the study in which she was an author as</p> <p>15 well as the Melling -- Melling study?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question, completely misstates her testimony.</p> <p>18 A. I -- I'm not aware that either one was</p> <p>19 deposed.</p> <p>20 Q. Don't you think that that would be important</p> <p>21 to know when you're relying on things such as these</p> <p>22 two studies?</p> <p>23 MR. GORDON: Same objection.</p> <p>24 A. I -- I don't have any information about it.</p> <p>25 Q. Well you testified previously that you think</p>	<p style="text-align: right;">Page 76</p> <p>1 Did you ever say to the lawyers for 3M, "I'd</p> <p>2 like to know all the depositions that have been taken</p> <p>3 in this case?"</p> <p>4 A. No.</p> <p>5 Q. Or "I would like to see any evidence that</p> <p>6 might exist that undercuts what I'm writing in my</p> <p>7 report?"</p> <p>8 A. I was writing a -- a report and I thought I</p> <p>9 had much of the information. If you're telling me</p> <p>10 that there's important information that I don't have,</p> <p>11 I would be interested to know.</p> <p>12 (Exhibit 7 was marked for</p> <p>13 identification.)</p> <p>14 BY MS. CONLIN:</p> <p>15 Q. I've handed you, sir, what's been marked as</p> <p>16 Borak Deposition Exhibit No. 7, which is the</p> <p>17 deposition of Andrea Kurz dated January 12th, 2017,</p> <p>18 and you'll see that on that first page, internal page</p> <p>19 four, it lists Mr. Gordon, the lawyer sitting next to</p> <p>20 you, present at the deposition, as well as a Mr.</p> <p>21 Assaad.</p> <p>22 Have you seen this before?</p> <p>23 A. I don't believe I have.</p> <p>24 Q. Okay. Okay. If you can take a look at page</p> <p>25 one seven -- internal page 177, which is the last page</p>
<p style="text-align: right;">Page 75</p> <p>1 it's important when you're undertaking an</p> <p>2 epidemiologic study, particularly one that relates to</p> <p>3 association or causation, to have all the information.</p> <p>4 Did you ask for all the information that might be</p> <p>5 pertinent to your decision?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 A. I -- I don't know that there even is such</p> <p>9 information to have asked for.</p> <p>10 Q. Well did you tell Mr. Gordon, the lawyer for</p> <p>11 3M, "If I'm going to undertake this, I want to look at</p> <p>12 all the evidence that's been accumulated by the</p> <p>13 parties in this case?"</p> <p>14 A. I --</p> <p>15 It was understood that I could ask for</p> <p>16 whatever I thought I needed. I didn't know that there</p> <p>17 was ever a question of those two articles. They've</p> <p>18 been cited repeatedly. I've never seen them</p> <p>19 retracted. The index of the National Library of</p> <p>20 Medicine does not indicate that they have been</p> <p>21 qualified, so it's not my understanding that I was</p> <p>22 citing here problematic papers, and I don't think I</p> <p>23 have any reason to know that they were reviewed by</p> <p>24 anybody as problematic.</p> <p>25 Q. But you didn't ask the question. Did you --</p>	<p style="text-align: right;">Page 77</p> <p>1 of this document, --</p> <p>2 A. Yes.</p> <p>3 Q. -- and they're talking there about the study</p> <p>4 which you've listed as reference number three, and she</p> <p>5 says at the top of the page:</p> <p>6 "...it's a retrospective study and not one</p> <p>7 of the best-done either. So you --</p> <p>8 "Question: Based on in today's standards.</p> <p>9 "Answer: Based on in today's standards.</p> <p>10 "Okay. It might have been good standards</p> <p>11 back in 1996."</p> <p>12 Then it says, "Okay. And Dr. Sessler has</p> <p>13 mentioned in an e-mail before, in today's standards</p> <p>14 and with respect to reliability of studies, that he</p> <p>15 probably wouldn't have published the 1996 Kurz paper.</p> <p>16 Do you agree with him?</p> <p>17 "Absolutely.</p> <p>18 "Okay.</p> <p>19 "I would not have either."</p> <p>20 And if you look down at the bottom of page</p> <p>21 178 with reference to the Melling study, "It was an</p> <p>22 okay study for" --</p> <p>23 Starting -- page 178, starting at line 16:</p> <p>24 "Question: Do you think Melling was a good</p> <p>25 study?"</p>

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<p style="text-align: right;">Page 78</p> <p>1 "Answer: It was an okay study for the time. 2 "Question: Would you agree with me that it 3 wouldn't be publishable today? 4 "Answer: I absolutely would agree with 5 you." 6 A. You seem to have read it correctly. 7 Q. Okay. And if you look at the top of page 8 179, question at line 16: 9 "In today's scientific standards, there is 10 no reliable evidence that supports that maintaining 11 normothermia reduces the incidence of infection. 12 "Answer: That is correct." 13 Were you aware of that testimony before 14 today? 15 A. No, I was not. 16 Q. Did you do any investigation into the 17 Sessler -- or the Kurz/Sessler and Melling papers as 18 part of your opinions in this case? 19 A. I did not. 20 Q. Do you have an opinion on whether the use of 21 Bair Hugger increases the number of particulates over 22 a surgical site? 23 A. I have seen papers that suggest it does and 24 I have seen papers that suggest it might not. 25 Q. My question was different. Do you have an</p>	<p style="text-align: right;">Page 80</p> <p>1 A. I have read both of those papers. I have no 2 expert opinions about the question you ask. 3 Q. Okay. And you don't cite to or rely on 4 Darouiche or Stocks in connection with your 5 conclusions that are rendered in your -- or contained 6 in your June 2nd expert report. 7 A. Yes, that is correct. It was my opinion 8 that it was the link between the use of Bair Hugger 9 and the evidence of infection that mattered. 10 Q. Okay. But you also understand as an 11 epidem -- as someone studying epidemiology that you 12 have to look at the chain of infection; right? 13 There's a concept is called biological plausibility; 14 correct? 15 A. Well I -- 16 MR. GORDON: Object to the form of the 17 question. 18 A. I -- I understand that there is such an 19 issue of plausibility and potentiality, yes. 20 Q. Okay. And you didn't think it was important 21 to understand whether, by way of mechanism, the Bair 22 Hugger would increase the number of particulates over 23 the surgical site? 24 A. I -- I understood the argument that there 25 might be such a mechanism. I opined, based upon the</p>
<p style="text-align: right;">Page 79</p> <p>1 opinion on whether the use of Bair Hugger increases 2 the number of particulates over a surgical site? 3 A. I -- I don't have such an opinion. 4 Q. One way or another. 5 A. One way or another. 6 Q. Okay. Have you done any investigation into 7 that issue? 8 A. I -- I have read a number of papers, but it 9 is not my area of expertise, and I read them only 10 because occasionally -- they've occasionally been 11 cited by some of the others in this case. 12 Q. Okay. Do you think that, in connection with 13 reaching a conclusion, which you did, that there is no 14 association between the use of Bair Hugger and a risk 15 of infection, that it would be important to ascertain 16 whether use of the Bair Hugger increases the number of 17 particulates over the surgical site? 18 A. I -- I rendered my opinion on the basis of 19 my understanding of evidence linking Bair Hugger and 20 infection, not based upon Bair Hugger and particulates 21 per se. 22 Q. So you haven't done any investigation, for 23 example, into the paper -- published papers by Stocks 24 or Darouiche as whether increased particulates over a 25 surgical site can increase the risk of infection.</p>	<p style="text-align: right;">Page 81</p> <p>1 evidence, that there was a link between Bair Hugger 2 and infections, not on whether there was some 3 intermediary process that might be linked. 4 Q. Well how do you understand how the Bair 5 Hugger might increase the risk of infection? 6 A. I understand that there are theoretical 7 mechanisms that might be at play, and I would frankly 8 defer that to Dr. Wenzel. I was not asked to opine 9 about the theoretical mechanisms and I have not opined 10 about them. 11 Q. So your opinion that there is no association 12 between Bair Hugger and risk of infection is divorced 13 from a concept of whether it increases particulates 14 over the surgical site. 15 MR. GORDON: Object to the form of the 16 question. 17 A. I -- I -- there -- 18 There are two parts of an answer. The first 19 one is that you misdescribe my opinion, and the second 20 is that I -- my opinion was not dependent upon whether 21 there was or wasn't a change in the particulate load. 22 Q. Okay. And so if there was a substantial 23 increase of particulates over the surgical site caused 24 by the Bair Hugger, that would not inform your opinion 25 one way or another.</p>

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<p style="text-align: right;">Page 82</p> <p>1 A. I -- I -- I think I described that in my 2 report, and I can turn to it if you like. It had to 3 do with the end of my discussion of causality, and I 4 said that in the absence of evidence -- 5 I perhaps should look at it so I don't badly 6 paraphrase it, if you don't mind. 7 Q. Sure. I think you're on page 21, paragraphs 8 68 and 69. 9 A. You know it better than I do. I'm 10 impressed. Thank you. If others would read my work 11 as well as you do, I would be flattered. 12 In paragraph 71 I wrote, "In the absence of 13 valid evidence of a causal association between Bair 14 Hugger and SSI, it can only be said that the 15 mechanistic studies are coherent with a hypothetical 16 increase in SSI." And "Hypothetical associations," I 17 believe, "are not sufficient to sustain an inference 18 of causation." 19 Q. Okay. 20 A. I think that's what you were asking me 21 about. 22 Q. Not necessarily. 23 My question is: And so if there was a 24 substantial increase in the number of particulates 25 over the surgical site caused by the Bair Hugger, that</p>	<p style="text-align: right;">Page 84</p> <p>1 you really meant deep joint infection? 2 A. If you point to them, I'll try to clarify. 3 Q. Well -- 4 A. I may have used it ambiguously. 5 Q. Okay. Do you understand the difference 6 between a -- what's known to doctors as a deep 7 incisional infection and a deep joint infection? 8 A. I -- 9 MR. GORDON: Object to the form of the 10 question. 11 A. I think I do, but maybe you will clarify. 12 Q. Okay. What's your understanding? 13 A. I think that a deep infection of a wound, if 14 we're talking about non-arthroplastic, it's not in the 15 joint, it's not orthopedic, and is in the deeper 16 tissues of the surgical area; and a joint infection 17 seems to be fairly straightforward, it is in the area 18 of the joint. 19 Q. Do you know how -- 20 Did you do any investigation as to how deep 21 joint infections occur? 22 A. Not per se. 23 Q. Do you have any understanding of bio -- the 24 term "biofilm" as it relates to infectious organisms 25 on prosthetic joints?</p>
<p style="text-align: right;">Page 83</p> <p>1 would not inform your opinion one way or the other. 2 A. It would inform thinking about a 3 hypothetical association. In the absence of evidence 4 linking Bair Hugger and surgical infections, the 5 presence of particulates, as you describe them, would 6 be interesting but insufficient to point to causation. 7 Q. Okay. I wasn't asking you about causation, 8 but -- 9 Do you have an opinion of whether an 10 increased number of particles over a surgical site 11 creates an increased risk of infection? 12 A. I don't have such an opinion. I am not an 13 expert in that domain. I understand the logic of it, 14 but it's not an area that I know well enough to opine. 15 Q. You talk about SSIs or surgical-site 16 infections throughout your report. Could you give me 17 a definition of that? 18 A. In the context, I was looking specifically 19 at infections following -- I -- I principally was 20 thinking about infections following arthroplastic 21 surgery, and my intent was to speak to deep 22 infections, but I think in some places I may have used 23 the term more generally to speak of infections at 24 surgical sites. 25 Q. Okay. So where I see "SSI" in your report,</p>	<p style="text-align: right;">Page 85</p> <p>1 A. I have read about bio -- biofilms. 2 Q. Have you done any investigation into whether 3 or not antibiotics are effective in connection with a 4 biofilm formed on a prosthetic? 5 A. It is my understanding that biofilms can 6 make antibiotics less effective. 7 Q. My question was: Did you do any 8 investigation into that? 9 A. I -- I read about that. 10 Q. Okay. But you didn't undertake an 11 exhaustive literature review in connection with that. 12 A. I -- I -- I did not do an exhaustive 13 literature review. My understanding was that Dr. 14 Wenzel would do that. 15 Q. Okay. Did you meet with Dr. Wenzel other 16 than this meeting in DC on May 8th? 17 A. No, we've never met since then. 18 Q. Okay. How long did the meeting go? 19 A. I would guess three or four hours, but I'm 20 not sure. 21 Q. Have you spoken to him since then? 22 A. I think I spoke to him once. 23 Q. What was that in connection with? 24 A. I think I was asking him a question about a 25 definition of surgical infections.</p>

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<p style="text-align: right;">Page 86</p> <p>1 Q. What did he tell you?</p> <p>2 A. I don't recall his answer. I'm sorry.</p> <p>3 Q. Did you see his report before it went in?</p> <p>4 A. I think I did, yes.</p> <p>5 Q. You haven't looked at any of the expert</p> <p>6 reports that have been proffered either by 3M or the</p> <p>7 plaintiffs in connection with computational fluid</p> <p>8 dynamics?</p> <p>9 A. Yes, I have not looked at those reports.</p> <p>10 Q. Okay. Were you aware that corporate</p> <p>11 representatives for 3M have testified in this case</p> <p>12 that the use of the Bair Hugger increases the number</p> <p>13 of particles over the surgical site?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. I -- I don't think I'm aware of that. Maybe</p> <p>17 I heard it. I don't know. I haven't read it.</p> <p>18 MS. CONLIN: If we could pull out Exhibit 11</p> <p>19 from yesterday, Mr. Stirewalt.</p> <p>20 (Holford Exhibit 11 handed to the witness.)</p> <p>21 THE WITNESS: Thank you.</p> <p>22 Q. I've handed you what was marked during</p> <p>23 Professor Holford's deposition as Exhibit 11, which is</p> <p>24 an excerpt out of the 30(b)(6) deposition of Al Van</p> <p>25 Duren.</p>	<p style="text-align: right;">Page 88</p> <p>1 "Answer: In absolute numbers, yes.</p> <p>2 "Question: Yes. Okay. And you have no</p> <p>3 internal studies to refute that?</p> <p>4 "No, we don't."</p> <p>5 Do you see that?</p> <p>6 A. I do see that.</p> <p>7 Q. Okay. Did you ever investigate why 3M would</p> <p>8 be concerned about increased particulates over the</p> <p>9 sterile surgical site?</p> <p>10 A. I did not --</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question, assumes facts not evidence.</p> <p>13 MS. CONLIN: You may answer.</p> <p>14 A. I did not investigate that.</p> <p>15 Q. Okay. I take it it's because you didn't</p> <p>16 think it was important to the conclusions that you</p> <p>17 rendered; correct?</p> <p>18 A. I didn't know that it had been done.</p> <p>19 Q. Well now that you know it had been done, is</p> <p>20 that information you thought you should have had in</p> <p>21 connection with your opinions?</p> <p>22 A. I had determined early in this process,</p> <p>23 probably going back to that meeting in May, that I was</p> <p>24 not going to be dealing with the issue of particles,</p> <p>25 as you're describing them.</p>
<p style="text-align: right;">Page 87</p> <p>1 Have you met Mr. Van Duren before?</p> <p>2 A. No.</p> <p>3 Q. Have you met a single individual at 3M in</p> <p>4 connection with your work in this case?</p> <p>5 MR. GORDON: Non-lawyers you mean.</p> <p>6 A. Yeah. I met a Mr. Boone when you and I</p> <p>7 first met about a week ago, and I understood he was</p> <p>8 in -- in -- inside at 3M. But other than that, no, I</p> <p>9 don't think so.</p> <p>10 Q. You never talked with any of the folks that</p> <p>11 are involved with Bair Hugger at 3M.</p> <p>12 A. Not that I'm aware of.</p> <p>13 Q. Okay. And certainly not in connection with</p> <p>14 the opinions you rendered in this case.</p> <p>15 A. I don't think so.</p> <p>16 Q. Okay. If we can take a look on the back</p> <p>17 page of what's been previously marked as Holford</p> <p>18 Deposition Exhibit 11, and if you can direct your</p> <p>19 attention to the internal page 258, starting on line</p> <p>20 five, where the corporate representative for 3M was</p> <p>21 asked the following question:</p> <p>22 "Okay. Based on the data we have today,</p> <p>23 including the study funded by 3M as well as other</p> <p>24 studies, every single study indicates that Bair Hugger</p> <p>25 increases the particle count over the sterile field.</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. And you didn't think that was important to</p> <p>2 look at in connection with the opinions that you've</p> <p>3 rendered; correct?</p> <p>4 MR. GORDON: Object to the form of the</p> <p>5 question.</p> <p>6 A. Yes. In the absence of evidence that Bair</p> <p>7 Hugger caused joint infections, I did not think that</p> <p>8 the particle information mattered.</p> <p>9 Q. Why didn't it matter?</p> <p>10 A. Because infections were what mattered.</p> <p>11 Q. Well, do you know whether -- you --</p> <p>12 You understand that both Darouiche and</p> <p>13 Stocks and others have said that an increase of</p> <p>14 particulates equals -- or can equal an increase in the</p> <p>15 number of infectious organisms; correct?</p> <p>16 MR. GORDON: Object to the form of the</p> <p>17 question.</p> <p>18 A. I -- I have read some who have said that,</p> <p>19 and I have read others who apparently found no</p> <p>20 evidence of either increased particulates or bacteria,</p> <p>21 and I have read others who found no evidence of</p> <p>22 bacteria at all. I have not rendered an opinion on</p> <p>23 that particular body of literature.</p> <p>24 Q. You have no opinion on whether an increase</p> <p>25 in particulates over a surgical site can increase the</p>

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<p style="text-align: right;">Page 90</p> <p>1 risk of infection.</p> <p>2 A. I think it would matter greatly what kind of</p> <p>3 particulates. There are all kinds of issues there</p> <p>4 that I do not know with sufficient expertise.</p> <p>5 (Exhibit 8 was marked for</p> <p>6 identification.)</p> <p>7 THE WITNESS: Thank you.</p> <p>8 BY MS. CONLIN:</p> <p>9 Q. I have handed you, sir, what's been marked</p> <p>10 as Borak Exhibit 8, which is an e-mail from Michelle</p> <p>11 Hulse Stevens at 3M to a number of people at 3M.</p> <p>12 You've never met Dr. Hulse Stevens before?</p> <p>13 A. No.</p> <p>14 Q. Okay. And you see the subject is "FAW" --</p> <p>15 which is forced-air warming -- "aerobiology and the</p> <p>16 Orthopedic International Consensus Meeting on</p> <p>17 Prevention of Prosthetic Joint Infection." Do you see</p> <p>18 that?</p> <p>19 A. I do see that.</p> <p>20 Q. Okay. And she starts by saying, "All,</p> <p>21 "I sat in on the group addressing the OR</p> <p>22 environment to this consensus document. There is</p> <p>23 amazing concern about any particulates in the air</p> <p>24 during joint replacement surgery and almost uniform</p> <p>25 comment that forced-air warming increases particulates</p>	<p style="text-align: right;">Page 92</p> <p>1 panel would have raised.</p> <p>2 Q. Do you think it would be important if the</p> <p>3 people who are selling the Bair Hugger were concerned</p> <p>4 about it creating an increase of particulates in the</p> <p>5 air over the surgical site?</p> <p>6 A. It may have been a very appropriate thing</p> <p>7 for them to be concerned about.</p> <p>8 Q. But you didn't know that they were until</p> <p>9 today; correct?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question, it assumes facts not in evidence, mis -- and</p> <p>12 misconstrues the evidence.</p> <p>13 A. I've never seen this document before.</p> <p>14 Q. Okay. In your report you express no opinion</p> <p>15 on whether the Bair Hugger can create convective</p> <p>16 turbulence in the OR; correct?</p> <p>17 A. I rendered no such opinions.</p> <p>18 Q. Okay. And you haven't looked at any</p> <p>19 literature aside from McGovern that addresses that</p> <p>20 specific subject.</p> <p>21 A. I -- I -- I have read articles about it, but</p> <p>22 I have no opinion about it and I've rendered no</p> <p>23 opinion about it.</p> <p>24 Q. And I take it you didn't think that that was</p> <p>25 important in connection with the opinions that you've</p>
<p style="text-align: right;">Page 91</p> <p>1 in the air. They are so sensitive to this issue that</p> <p>2 they discussed the contribution of talking to</p> <p>3 particulates, and to the difference in squames</p> <p>4 shedding between male and female OR staff. They</p> <p>5 equate particulates with bacteria in the air and cite</p> <p>6 studies (do not have the citations) that support</p> <p>7 this." Do you see that?</p> <p>8 A. I've read that, yes.</p> <p>9 Q. Okay. And did you read this today for the</p> <p>10 first time?</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. This isn't a document that you saw in</p> <p>13 connection with your expert opinions in this case?</p> <p>14 A. I've never seen this before.</p> <p>15 Q. Do you think it would be important if the</p> <p>16 people who are selling the Bair Hugger are concerned</p> <p>17 that par -- there's an equation of particulates with</p> <p>18 bacteria in the air --</p> <p>19 MR. GORDON: Object --</p> <p>20 Q. -- and that they've cited to studies that</p> <p>21 support this?</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question, miscon -- misconstrues the document and the</p> <p>24 evidence.</p> <p>25 A. I -- I can understand the concern that this</p>	<p style="text-align: right;">Page 93</p> <p>1 expressed in your expert report.</p> <p>2 A. As I've explained, I thought that the link</p> <p>3 between Bair Hugger and surgical-site infections was</p> <p>4 the critical issue, and that's what I focused on.</p> <p>5 Q. But you didn't, in connection with that</p> <p>6 link, you didn't look at or investigate whether the</p> <p>7 use of the Bair Hugger can create particulates that</p> <p>8 can create that link.</p> <p>9 A. I -- I read that there was literature which</p> <p>10 addressed that, and I understood that others were</p> <p>11 going to address that.</p> <p>12 Q. So I take it if someone said there was a</p> <p>13 risk of airborne contamination with the Bair Hugger,</p> <p>14 you'd disagree with that.</p> <p>15 A. No. I don't have enough evidence to say</p> <p>16 that. I would say that there is no good evidence that</p> <p>17 use of the Bair Hugger causes surgical-site</p> <p>18 infections.</p> <p>19 Q. Well would you -- if --</p> <p>20 If someone said that there's a risk of</p> <p>21 airborne contamination with the Bair Hugger, would</p> <p>22 that be of import to you or not?</p> <p>23 A. It's of interest to me.</p> <p>24 Q. Okay. But you haven't seen anything that</p> <p>25 says that; right?</p>

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<p style="text-align: right;">Page 94</p> <p>1 A. I have seen papers that have indicated that 2 there were increased particulates and I have read 3 papers that said that there weren't. 4 (Discussion off the stenographic record.) 5 (Exhibit 9 was marked for 6 identification.) 7 BY MS. CONLIN: 8 Q. I've handed you, sir, what's been marked as 9 Borak Exhibit 9, which is a 510(k) summary of safety 10 and effectiveness dated January 10th, 1996 involving 11 FDA approval of the Bair Hugger 750. 12 Do you have any understanding of the 13 differences in designs between, for example, the 500 14 or the 750? 15 A. I've seen reference to it, but I don't know 16 what the differences are. And I don't know what a 17 510(k) is. 18 Q. 510(k) is when you are seeking abbreviated 19 approval through the FDA based on a predicate device. 20 A. Okay. 21 Q. So if you look at the first paragraph here, 22 it will say, last sentence under "SAFETY," "The 23 predicate device is the Bair Hugger Patient Warming 24 System, Model 500 Warming Unit." Okay? 25 A. I --</p>	<p style="text-align: right;">Page 96</p> <p>1 Do you see that? 2 A. I do. 3 Q. Okay. Now this was submitted in connection 4 with the Bair Hugger model 750. Have you ever seen 5 this before? 6 A. No. 7 Q. Okay. Would this be something that you 8 would view as important in connection with the 9 conclusions contained in your expert report in this 10 case? 11 A. As I've explained, my expert opinion was 12 based upon what I found as evidence linking Bair 13 Hugger with infections. So this is interesting, but 14 this is not evidence of infections. 15 Q. Well you understand that the mechanism of 16 infections is through airborne contamination; 17 correct, -- 18 MR. GORDON: Object -- 19 Q. -- sir? 20 MR. GORDON: Object to the form of the 21 question, assumes facts not in evidence. 22 A. I understand that that is an area that Dr. 23 Wenzel is going to be opining about, that I was not 24 going to opine about that, and so I have no opinion 25 about that.</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. GORDON: Object to the form of the 2 question. 3 A. I'm accepting that what you've read is 4 correct. I don't see it here, but that doesn't, I 5 think, matter. 6 Q. Well take a look at the last sentence under 7 "SAFETY." Do you see it says -- 8 A. Ah, yes. Okay. There I see it. 9 Q. -- "The predicate device..." 10 A. Okay. Thank you. 11 Q. Okay? 12 A. So what you're saying is this is a request 13 for a subsequent machine to be adopted based upon the 14 history of that predecessor, the predicate. 15 Q. Right. 16 A. Okay. 17 Q. Okay? And you see on the first page it 18 talks about "Summary of Safety;" correct? 19 A. Yes. 20 Q. Okay. And I'd like to direct your attention 21 to the back page of this exhibit. Do you see section 22 C. "Other Safety Concerns: 23 "1. Contamination. Airborne contamination 24 from air blown intraoperatively across the surgical 25 wound may result in airborne contamination."</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Well you understand when -- 2 When you've opined that there is no 3 association between the use of the Bair Hugger and 4 infection, you understand the mechanism by which 5 plaintiffs are alleging the infection occurs is 6 through airborne contamination; correct? 7 A. Well once again you have asked a question 8 which has two different parts of it. First of all, I 9 do not accept your description of my opinion. 10 Secondly, I'm not sure what the plaintiffs are 11 alleging. I understand there was discussion of the 12 airborne particulates as being a possible intermediary 13 in the development of infection. I have been looking 14 at the infections. 15 Q. Okay. And so you did no analysis as to 16 whether the Bair Hugger can create airborne 17 contamination; correct? 18 A. I think I've explained that I was not asked 19 and agreed that I would not be addressing and did not 20 do an investigation to determine whether that was so. 21 Q. Well how can you find that there is no 22 association between Bair Hugger and infections if you 23 didn't investigate the mechanism by which those 24 infections can occur? 25 MR. GORDON: Object to the form of the</p>

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<p style="text-align: right;">Page 98</p> <p>1 question.</p> <p>2 A. I think we earlier went over the fact that</p> <p>3 I've agreed that the presence of such intermediary</p> <p>4 mechanisms in the absence of infections poses an</p> <p>5 interesting hypothesis, but that in the absence of</p> <p>6 infections it is insufficient to show causation.</p> <p>7 Q. Well am I correct in stating that you didn't</p> <p>8 look at the issue, in connection with the conclusion</p> <p>9 you just stated, as to whether use of the Bair Hugger</p> <p>10 can create airborne contamination which can lead to</p> <p>11 infection?</p> <p>12 A. I -- I think I've already answered this but</p> <p>13 let's try it one more time. I have read a number of</p> <p>14 papers that had to do with the question of whether the</p> <p>15 Bair Hugger did or did not cause increase in airborne</p> <p>16 particulates, but I have no opinion as to whether that</p> <p>17 is the cause and whether that causes. My opinion</p> <p>18 rests upon whether there is evidence the Bair Hugger</p> <p>19 causes infection, and that is the basis of my opinion.</p> <p>20 Q. Can you answer my question? I'll read it</p> <p>21 back to you.</p> <p>22 Am I correct in stating that you didn't look</p> <p>23 at the issue, in connection with the conclusion you</p> <p>24 just stated, as to whether the use of the Bair Hugger</p> <p>25 can create airborne contamination which can lead to</p>	<p style="text-align: right;">Page 100</p> <p>1 question, so --</p> <p>2 A. I -- I am really trying to answer your</p> <p>3 question.</p> <p>4 Q. Okay.</p> <p>5 A. You're asking the same question, I think,</p> <p>6 repeatedly, but --</p> <p>7 Q. No, because you're --</p> <p>8 Well if I am, it's because you're not</p> <p>9 answering it. My ques --</p> <p>10 MR. GORDON: Well move -- move to strike</p> <p>11 counsel's commentary.</p> <p>12 Q. Did you find -- did you find it important at</p> <p>13 all, looking at this document today, to see that the</p> <p>14 manufacturer of the Bair Hugger 750 warned in an FDA</p> <p>15 document about the risk of airborne contamination</p> <p>16 through use of the Bair Hugger?</p> <p>17 A. I think it's interesting.</p> <p>18 Q. Is this something that you wish you would</p> <p>19 have had before you rendered your opinions in this</p> <p>20 case, or are you saying it's of no import?</p> <p>21 A. I'm saying that in the absence of evidence</p> <p>22 of infections, the fact that this happens doesn't seem</p> <p>23 to me to be central to my opinions.</p> <p>24 Q. Okay. Why would they be warning about</p> <p>25 airborne contamination if it wasn't increasing a risk</p>
<p style="text-align: right;">Page 99</p> <p>1 infection?</p> <p>2 A. And the answer was I read articles and</p> <p>3 reports that were relevant to the question, but I did</p> <p>4 not render an opinion, and I do not have one to offer</p> <p>5 you now as to whether Bair Hugger causes -- and your</p> <p>6 phrase was --</p> <p>7 Q. Create airborne contamination which can lead</p> <p>8 to infection.</p> <p>9 A. Yes. I do not have an opinion as to whether</p> <p>10 it does that because it is my opinion that there is</p> <p>11 not sufficient evidence that it causes infection.</p> <p>12 Q. Well if you didn't look at the issue of</p> <p>13 whether it causes airborne contamination, how could</p> <p>14 you have reached your conclusion that it doesn't cause</p> <p>15 infections?</p> <p>16 A. Because I --</p> <p>17 MR. GORDON: Object to the form of the</p> <p>18 question.</p> <p>19 A. I have looked at the information that I</p> <p>20 believe is available. I don't think I'm missing any</p> <p>21 of the information that has to do with whether the</p> <p>22 Bair Hugger causes infection. And other than two</p> <p>23 studies, which I believe to be inadequate, I find no</p> <p>24 evidence that it causes infection.</p> <p>25 Q. You -- you're -- you're not answering my</p>	<p style="text-align: right;">Page 101</p> <p>1 of infection?</p> <p>2 MR. GORDON: Object to the form of the</p> <p>3 question, it assumes facts not in evidence, lack of</p> <p>4 foundation.</p> <p>5 A. The question is "Why would they have done</p> <p>6 it?" I think they were required to. And I don't</p> <p>7 think that there was evidence at that time that this</p> <p>8 was leading to infections.</p> <p>9 Q. Well okay. First of all, you have no idea</p> <p>10 because you just told me you don't know what a 510(k)</p> <p>11 is, so when you state that, you have no idea whether</p> <p>12 they're required to do that or not.</p> <p>13 A. Yes, but --</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. -- your question -- your question was</p> <p>17 whether I had an opinion about why they did it. I</p> <p>18 think that was your question.</p> <p>19 Q. Do you see where it says, "Prevention of</p> <p>20 airborne contamination" underneath the safety</p> <p>21 concerns, and it says, "Prevention of airborne</p> <p>22 contamination: All Bair Hugger Blankets designed for</p> <p>23 use in the operating room feature a tape barrier which</p> <p>24 prevent air from migrating toward the surgical site."</p> <p>25 Do you see that?</p>

26 (Pages 98 to 101)

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<p style="text-align: right;">Page 102</p> <p>1 A. Yes. Point to which line you have just read 2 to me so I'm sure that I am on track here. 3 Q. Right under "Prevention of airborne 4 contamination." Right? 5 A. Yes, I see that paragraph. 6 Q. Colon, "All Bair Hugger Blankets designed 7 for use in the operating room feature a tape barrier 8 which prevent air from migrating toward the surgical 9 site." 10 A. I read that, yes. 11 Q. Okay. Why would the manufacturer of a Bair 12 Hugger have a tape barrier to prevent air from 13 migrating toward the surgical site? 14 MR. GORDON: Objection, lack of foundation. 15 A. I -- I'm -- I'm conjecturing. You 16 understand I'm not an engineer, I'm not a biomedical 17 expert. I assume they're doing it to keep air from 18 leaving the blanket, but I -- that's just a 19 conjecture. 20 Q. And that would be -- 21 And this is, of course, under the section 22 where they're talking about concern over airborne 23 contamination; correct? 24 A. That is the caption, yes. 25 Q. Okay. So did you do any investigation into</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Document speaks for itself. 2 A. Okay. 3 Q. You haven't looked at it. I'll move on. 4 MS. CONLIN: Can you pull out Exhibit 30, 5 please, Mr. Stirewalt, from yesterday. 6 (Holford Exhibit 30 handed to the witness.) 7 MS. CONLIN: That actually may not be the 8 right one. 9 (Discussion off the stenographic record.) 10 BY MS. CONLIN: 11 Q. I've handed you, sir, what's been marked as 12 Deposition Exhibit 30, Holford Deposition Exhibit 30. 13 MS. CONLIN: And perhaps if you could hand 14 him, Mr. Court Reporter, Exhibit 31 as well. 15 (Holford Exhibit 31 handed to the witness.) 16 Q. I've handed you, sir, what's been previously 17 marked as Holford Deposition Exhibits 30 and 31, which 18 are excerpts from the CDC Department of Health and 19 Human Services, Centers for Disease Control, 20 Healthcare Infection Control Practices Advisory 21 Committee. Have you seen -- 22 Had you seen Exhibits 30 or 31 prior to the 23 time you rendered your expert opinions in this case? 24 A. I don't think I've read them, no. 25 Q. Okay. Did you see them yesterday after</p>
<p style="text-align: right;">Page 103</p> <p>1 whether airborne contamination could occur over the 2 surgical site if a tape barrier weren't in place? 3 A. I did not look at that question 4 specifically. 5 Q. Okay. And then you see it talks about 6 "Additionally, air is filtered through a .2 micron 7 filter." Do you see that? 8 A. I do see that. 9 Q. Do you know why a manufacturer would be 10 concerned about filtering air before sending it 11 through the Bair Hugger? 12 MR. GORDON: Object to the form of the 13 question. 14 A. I -- I can imagine, but it's purely 15 conjecture. 16 Q. It wasn't something that you investigated in 17 connection with the opinions that you've rendered; 18 correct, sir? 19 A. Yes, that's correct. 20 Q. And you didn't do any investigation into the 21 filter efficiency of the Bair Hugger; correct? 22 A. No, I specifically did not look at the 23 filter efficiency of the Bair Hugger. 24 Would -- would you finish reading that 25 paragraph?</p>	<p style="text-align: right;">Page 105</p> <p>1 Mr. -- or after Professor Holford's deposition was 2 taken? 3 A. We may have spoken of it. I -- I may even 4 have seen them, but I didn't read them. 5 Q. Okay. So at the time you -- 6 And -- and you've, I think, previously 7 testified you think the CDC is a very reputable 8 organization; correct? 9 A. Yeah. But it's a very big organization, 10 which means that it does have components that make 11 mistakes. And I have worked for CDC and I have 12 respect for it. 13 Q. Okay. And were you aware at the time that 14 you rendered your expert opinions in this case that 15 the CDC Advisory Committee on Healthcare Infection 16 Control Practices had suggested that nothing that 17 blows air should be in an operating room? 18 MR. GORDON: Object to the form of the 19 question, misstates the evidence, assumes facts not in 20 evidence. 21 A. I -- I am aware that they made that 22 statement at some time in the past, yes. 23 Q. Okay. Were you aware of it at the time you 24 rendered your expert opinions in this case? 25 A. Not specifically.</p>

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<p style="text-align: right;">Page 106</p> <p>1 Q. Okay. Did you do an investigation, once you 2 found that out, as to why the CDC was recommending 3 that nothing that blows air should be in an operating 4 room, if possible? 5 MR. GORDON: Object to the form of the 6 question, misstates the evidence, assumes facts not in 7 evidence. 8 A. My understanding from looking at this and 9 discussions with Mr. Gordon last night -- or yesterday 10 was that there was a subsequent algorithm or -- or -- 11 or structure that addressed that, and that the concern 12 the CDC had in -- or HICPAC had at that time concerned 13 blowers that had interfaces with -- with water 14 reservoirs that were wet, and I understand the concern 15 was probably related to a cluster of atypical 16 Mycobacterium infections in the cardiothoracic 17 surgical area. 18 Q. Can you answer my question? 19 A. Well ask me your question again then. 20 Q. Sure. 21 Did you do any investigation, prior to the 22 time you rendered your opinion in this case, as to why 23 the CDC was recommending that nothing that blows air 24 should be in an operating room, if possible? 25 MR. GORDON: Same objections, also now asked</p>	<p style="text-align: right;">Page 108</p> <p>1 reaching those opinions, you had to satisfy the issues 2 or find them not to be of interest or import that 3 cultures had been taken in many Bair Hugger devices 4 with infectious microbes. 5 A. I -- 6 MR. GORDON: Object to the form of the 7 question. 8 A. I understand that there have been such 9 studies done. I have no evidence that that has led or 10 been associated with infections. 11 Q. Were you aware that there was an 12 Acinetobacter baumannii outbreak that was traced to 13 the Bair Hugger as well as another surgical unit in a 14 hospital? 15 MR. GORDON: Object to the form. 16 Are -- are you saying Acinetobacter? 17 MS. CONLIN: Yeah. 18 MR. GORDON: Object to the form of the 19 question, assumes facts not in evidence. 20 A. I -- I don't know that I'm aware of that. 21 Maybe I have read it. I don't recall. 22 Q. Okay. So it wasn't anything that informed 23 your opinions. 24 A. It did not inform my opinions. 25 Q. You weren't aware that there was an</p>
<p style="text-align: right;">Page 107</p> <p>1 and answered. 2 A. I think I answered that no, I had not looked 3 at this prior to rendering my report. 4 Q. Do you know whether the CDC would be 5 concerned about airborne contamination that could 6 infect a patient on an operating table? 7 A. It would seem reasonable that they might be 8 concerned about that. 9 Q. But that isn't something that you reviewed 10 prior to yesterday. 11 MR. GORDON: Objection, asked and answered. 12 A. Yes. 13 Q. Now you don't in your expert report deal at 14 all with the reported issues of culturing of microbes 15 within a Bair Hugger; correct? 16 A. Correct. 17 Q. And I take it you don't think that the 18 presence of microbes within a Bair Hugger can pose a 19 risk to a patient; correct? 20 A. No, I didn't say that. 21 Q. Well risk of infection to a patient. 22 A. I said that there was, to my knowledge, no 23 good evidence that use of the Bair Hugger caused 24 infections. 25 Q. And my point was: In connection with</p>	<p style="text-align: right;">Page 109</p> <p>1 Acinetobacter outbreak in Kentucky and they were able 2 to trace the organism back to the Bair Hugger as well 3 as another piece of equipment in the OR? 4 A. I -- I would be happy to look at that if you 5 have information about it. I'm not aware of it off 6 the top of my head. 7 Q. Okay. And it wasn't something that you 8 looked at in connection with rendering your expert 9 opinions in this case. 10 A. No, not specifically. 11 Q. Okay. Do you believe or have an opinion as 12 to whether the presence of infectious microbes being 13 harbored in a Bair Hugger unit can create a risk of 14 infection for a pa -- a patient? 15 MR. GORDON: Object to the form of the 16 question. 17 A. It -- it seems reasonable that it could. 18 Q. But you didn't look at it. 19 MR. GORDON: Object to the form of the 20 question. 21 A. I looked to see whether there was evidence 22 that use of the Bair Hugger had raised significantly 23 the risk of infection -- 24 Q. Right. But you -- 25 A. -- in orthopedic surgeries.</p>

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<p style="text-align: right;">Page 110</p> <p>1 Q. But you didn't investigate all the ways in 2 which it could cause that increase in infections. 3 A. No, no, no. I thought about them and I read 4 about them, but that was not part of my opinion. 5 Q. Well when you found that there wasn't 6 sufficient evidence for an association to exist 7 between the use of the Bair Hugger and an increased 8 risk of infection, is it your opinion that it was just 9 based on your review of McGovern? 10 A. Oh, no, no, it was not limited to my review 11 of McGovern. 12 Q. Well as an epidemiology analysis, you have 13 to look at all of the evidence that might create a 14 risk for a patient; correct? 15 A. Yes. And we go back to an answer I gave you 16 earlier -- I may not be answering your question, and I 17 apologize in advance -- but I said that absent valid 18 evidence of a causal association between Bair Hugger 19 and SSI, it can only be said that mechanistic studies 20 are coherent with a hypothetical increase, and what 21 you're posing to me is a hypothetical increase due to 22 a mechanism, and I agreed with you, it is hypothetical 23 and hypothetically relevant. 24 Q. But you didn't look at any of the documents 25 that might -- we'll go -- strike that.</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. But still you have to look at the evidence 2 to reach the conclusion, sir. 3 A. I -- I -- 4 Q. We just looked at a bunch of documents today 5 you've never seen. 6 A. I -- 7 The opinion I render is based on whether or 8 not there is evidence of infection, not whether or not 9 there is evidence of a hypothetical mechanism. And we 10 will not be able to resolve this difference. You 11 would like me to say -- I think you would like me to 12 say that the hypothetical mechanism is sufficient to 13 reach a causal conclusion, and it is my opinion that 14 it is not. 15 Q. I wasn't asking you that. I'm trying to 16 get -- 17 A. In that case, I withdraw the answer. 18 Q. I'm trying to get a sense of what you did in 19 connection with reaching your conclusions as expressed 20 in your report, and I've been probing that area, which 21 is what I'm asking you about. 22 MR. GORDON: And he's told you. 23 Q. So -- 24 I don't know if you answered this or not. 25 You don't believe there is reason to be concerned</p>
<p style="text-align: right;">Page 111</p> <p>1 You agree with me, and I think you did 2 earlier, that association is, at the end of the day, a 3 matter of scientific judgment; correct? 4 A. You read me a statement that said that and I 5 said I didn't disagree with it. 6 Q. Right. You agree with it. 7 A. It requires judgment. 8 Q. Right. 9 A. It's not a matter of judgment. 10 Q. And in exercising that judgment, you didn't 11 investigate all the ways in which a Bair Hugger can 12 actually increase the risk of infection for a 13 plaintiff -- or a patient. 14 A. I -- I really apologize. We are banging 15 intellectual heads together on this particular issue. 16 I'm telling you that I read a lot and I am 17 aware of the hypothetical ways in which Bair Hugger 18 might contribute to infections. I don't have an 19 opinion as to whether any of those hypothetical 20 mechanisms are in fact causal, and I have said that 21 absent evidence that it causes infection, all of those 22 mechanisms are simply hypothetical. So when you ask 23 whether I have considered them, the answer is yes. 24 Did it contribute to my opinion? No, absent the 25 evidence of infections caused by Bair Hugger.</p>	<p style="text-align: right;">Page 113</p> <p>1 about pathogens harbored in the Bair Hugger machine 2 itself. 3 A. Oh, I don't think it's a good idea to harbor 4 pathogens in the Bair Hugger machine. 5 Q. Did you look at any of the documents that 6 related to -- strike that. 7 (Exhibit 10 was marked for 8 identification.) 9 BY MS. CONLIN: 10 Q. I've handed you, sir, what's been marked as 11 Deposition Exhibit No. 10, which is a series of 12 internal e-mails produced by 3M in the case. I'd like 13 to direct your attention to the second page at the 14 bottom. 15 A. Bear with me. I'm just looking to see 16 things like dates and so forth. And let me just -- 17 Q. Dated March 3rd, 2009. 18 A. Right. Oh, 2009. That's what I was looking 19 at. Yes, please go ahead. 20 Q. Okay. So if you can take a look at the last 21 page, please, bottom e-mail from Judy Hodges to Rick 22 Mathieu, "Subject: Bair Hugger," reads, "Rick, 23 "We have a model 750 unit, serial number 24 19137 that has cultured positive for Acinetobacter. 25 We are looking for directions for proper cleaning/</p>

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<p style="text-align: right;">Page 114</p> <p>1 disinfecting this machine, inside and out." 2 And if we can look, then, there's a series 3 of e-mails. When you look back to the first page, Al 4 Van Duren -- in the middle of the page, Al Van Duren 5 writes to Mark Scott with a cc to Gary Hansen and Dave 6 Westlin. 7 Do you know who any of those people are, by 8 the way? 9 A. No. 10 Q. Okay. And it says, "Do not scrap the unit. 11 "Remove and discard the filter (in the 12 biohazardous waste)." 13 Do you see that? 14 A. I do. 15 Q. Why -- why do you think that representatives 16 for 3M would be concerned about changing out a filter 17 when a machine has tested positive for Acinetobacter? 18 MR. GORDON: Object to the form of the 19 question, and lack of foundation. 20 A. I -- I can -- I can only conjecture. I 21 think that if there were bacteria in the machine, then 22 there might be bacteria on the filter, and it's 23 possible that the machine but not the filter can be 24 cleaned, but I don't know. 25 Q. Do you think they were warned -- warned</p>	<p style="text-align: right;">Page 116</p> <p>1 A. I don't think I did. 2 Q. Or what 3M did in connection with those 3 reports coming in from the field? 4 MR. GORDON: Object to the form of the 5 question. 6 A. No, I don't think so. 7 Q. Okay. And you don't know and didn't do 8 investigation whether they were concerned about 9 airborne contamination consistent with the FDA 10 document we looked at earlier. 11 MR. GORDON: Object to the form of the 12 question. 13 A. I -- I think you have shown me documents 14 that suggest that they had concerns, but I don't know. 15 MS. CONLIN: Okay. Why don't we take a 16 break there. 17 THE REPORTER: Off the record, please. 18 (Recess taken.) 19 BY MS. CONLIN: 20 Q. You can direct your attention, sir, to page 21 four of your expert report, Borak Exhibit 1. In the 22 first full paragraph you say, "But as discussed below, 23 there's insufficient evidence to demonstrate that 24 forced-air warming increases the probability of deep 25 joint infection under either scenario. That was the</p>
<p style="text-align: right;">Page 115</p> <p>1 of -- or worried about airborne contamination that 2 might cause an infection in a patient? 3 MR. GORDON: Lack -- 4 Objection, lack of foundation. 5 A. I think they were concerned about how to 6 clean the machine and they removed a filter and threw 7 it away in the biohazards waste. I'm guessing that 8 they threw it away because they couldn't clean it, but 9 I don't know if that's true. 10 Q. Can you answer my question? 11 A. I have no knowledge here or no information 12 here as to whether this has to do with airborne 13 hazards. 14 Q. My reading that, do you think they were 15 worried about airborne contamination that might infect 16 a patient? 17 MR. GORDON: Object to the form of the 18 question, lack of foundation. 19 A. I -- I don't know. I assume that would have 20 been among the myriad thoughts that might have been, 21 but I don't know. 22 Q. Okay. Did you look at any internal 23 documents about -- from 3M about machines that had -- 24 were coming out of the field that were testing 25 positive for various infectious microbes?</p>	<p style="text-align: right;">Page 117</p> <p>1 conclusion of the recent CDC Guideline for 2 Professional -- for Prevention of Surgical Site 3 Infection." Do you see that? 4 A. Yes. 5 Q. And then you say, "Likewise, the nonprofit 6 ECRI recently concluded: 7 "Based on our focused systematic review of 8 the published literature, we believe that there is 9 insufficient evidence to establish that the use of 10 forced-air warming systems leads to an increase in 11 SSIs compared to other warming methods." 12 Do you see that? 13 A. I do. 14 Q. And that was something that you reviewed and 15 relied on in connection with your expert opinion in 16 this case. 17 A. I cited it, yes. 18 Q. By citing it, you relied on it; correct? 19 A. That's correct. 20 Q. Okay. Did you ask the attorneys for 3M, Mr. 21 Gordon or otherwise, for information that would show 22 3M's involvement in any of these publications that are 23 coming out? 24 A. No. 25 Q. Did you think that was anything that would</p>

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<p style="text-align: right;">Page 118</p> <p>1 be important if you're relying on certain studies?</p> <p>2 A. I would not have thought of that as an issue</p> <p>3 with regards to the CDC guideline.</p> <p>4 With regards to ECRI, I did some web</p> <p>5 searching on it, discovered it was an organization</p> <p>6 that was perhaps 50 or more years old, that it had a</p> <p>7 very extensive participation. I looked at its board</p> <p>8 and I think maybe senior staff, whatever. But it</p> <p>9 seemed to me to be more than a public-relations</p> <p>10 effort. I was concerned because it was not a group</p> <p>11 that I normally deal with at great length.</p> <p>12 Q. Was the ECRI publication something that was</p> <p>13 provided to you by the attorneys for 3M?</p> <p>14 A. It's likely, but I'm not -- I don't remember</p> <p>15 specifically.</p> <p>16 Q. Okay. It's possible that it came from 3M in</p> <p>17 the packet of materials that you reviewed?</p> <p>18 A. It is possible.</p> <p>19 Q. Okay. You don't have any independent</p> <p>20 recollection of finding it on your own.</p> <p>21 A. I -- I don't know whether it came up as a</p> <p>22 consequence of searching the web on forced-air warmers</p> <p>23 and Bair Huggers. May have, but I don't remember.</p> <p>24 Q. Okay. But it's quite possible it came from</p> <p>25 3M.</p>	<p style="text-align: right;">Page 120</p> <p>1 should be preventing them from doing their own</p> <p>2 testing, but rather to rely on published data." Do</p> <p>3 you see that?</p> <p>4 A. I see that statement.</p> <p>5 Q. Why do you think individuals at 3M didn't</p> <p>6 want ECRI to do their own testing with respect to the</p> <p>7 Bair Hugger?</p> <p>8 MR. GORDON: Objection, lack of foundation.</p> <p>9 A. I -- I don't know.</p> <p>10 Q. Would that concern you as an epidemiologist</p> <p>11 if the manufacturer was trying to prevent studies from</p> <p>12 going on?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question.</p> <p>15 A. I -- I don't know whether the motivation</p> <p>16 was -- was financial or otherwise.</p> <p>17 Q. Do you --</p> <p>18 Are you aware that outside doctors and</p> <p>19 advisors were suggesting to 3M that they do their own</p> <p>20 studies on the Bair Hugger and they refused?</p> <p>21 MR. GORDON: Object to the form of the</p> <p>22 question, lack of foundation.</p> <p>23 A. I'm not aware of that.</p> <p>24 Q. Well when you say there's insufficient</p> <p>25 evidence, did you ascertain whether the paucity of</p>
<p style="text-align: right;">Page 119</p> <p>1 A. It's possible.</p> <p>2 (Borak Exhibit 11 was marked for</p> <p>3 identification.)</p> <p>4 THE WITNESS: Thank you.</p> <p>5 BY MS. CONLIN:</p> <p>6 Q. I have handed you, sir, what's been marked</p> <p>7 as Borak Deposition Exhibit 11, which is an internal</p> <p>8 3M document, timeframe of February 6th and -- 5th, 6th</p> <p>9 and 7th, 2011, so this would have been prior to the</p> <p>10 time the ECRI publication came out that you reference</p> <p>11 in your report as reference number five. And if you</p> <p>12 can take a look at the top of it, it's an e-mail from</p> <p>13 Gary Hansen to Dave Westlin, Teri Woodwick-Sides, Jana</p> <p>14 Stender and John Rock.</p> <p>15 Do you know who any of those individuals</p> <p>16 are?</p> <p>17 A. I do not.</p> <p>18 Q. Okay. Do you know whether they were</p> <p>19 involved in the ECRI publication that you relied on?</p> <p>20 A. I don't recognize the names.</p> <p>21 Q. Were you aware that they were involved in</p> <p>22 the ECRI publication that you relied on?</p> <p>23 A. I am not aware.</p> <p>24 Q. Okay. You see it says, "I was thinking</p> <p>25 about this over the weekend. Our first step with ECRI</p>	<p style="text-align: right;">Page 121</p> <p>1 evidence as you've described is due to the fact that</p> <p>2 3M refused to do their own testing?</p> <p>3 MR. GORDON: Object to the form of the</p> <p>4 question, assumes facts not in evidence.</p> <p>5 A. I have no idea.</p> <p>6 Q. Were you aware that representatives from 3M</p> <p>7 actually met with ECRI before that publication?</p> <p>8 A. I am not aware.</p> <p>9 Q. Were you aware that ECRI sent that</p> <p>10 publication to 3M for comment before it was published?</p> <p>11 A. I am not aware.</p> <p>12 Q. Would that be something that you would have</p> <p>13 wanted to know?</p> <p>14 A. I would find it interesting.</p> <p>15 Q. Why would you find it interesting?</p> <p>16 A. Because I didn't know it before and it's an</p> <p>17 interesting facet.</p> <p>18 I don't know whether 3M rewrote it. Is that</p> <p>19 the implication of your question? I don't know what</p> <p>20 happened.</p> <p>21 Q. But why would you find it interesting?</p> <p>22 A. Because I did not know, prior to five</p> <p>23 minutes ago, that there was any correlation between 3M</p> <p>24 and ECRI.</p> <p>25 Q. Would it -- would it have been of interest</p>

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<p style="text-align: right;">Page 122</p> <p>1 for you to know that 3M representatives met with ECRI 2 officials for an in-person meeting on March 9th of 3 2011 in Philadelphia? 4 A. I -- I don't know enough to tell you whether 5 it's anything of interest. 6 Q. Were you aware that ECRI assured 3M that it 7 would be a confidential discussion? 8 A. I have no knowledge of any of this. 9 Q. Would that be something you would have 10 wanted to know when you relied on the ECRI publication 11 as evidence that forced-air warming doesn't increase 12 risk of infection? 13 A. I read the ECRI document and I looked at the 14 ECRI website to understand who ECRI was. That was all 15 that I knew. 16 Q. Can you answer my question. 17 A. You're asking me whether my opinion of their 18 document would have been changed by the fact that 19 they -- 20 Q. No. 21 A. -- met in Philadelphia confidentially. 22 Q. That's not what I asked. It was: Would the 23 fact that 3M officials met with ECRI in confidential 24 discussions prior to the publication have been 25 something that you would have wanted to know when you</p>	<p style="text-align: right;">Page 124</p> <p>1 A. I -- I don't know whether that was true and 2 I didn't know it. 3 (Exhibit 12 was marked for 4 identification.) 5 THE WITNESS: Thank you. 6 BY MS. CONLIN: 7 Q. I've handed you, sir, what's been marked as 8 Deposition Exhibit 12, which is a series of e-mails 9 between Gary Hansen and Dan Sessler. 10 Do you know who Mr. Sess -- Dr. Sessler is? 11 (Glass of liquid spills on table.) 12 MS. CONLIN: Let's go off the record. 13 THE REPORTER: Off the record, please. 14 (Recess taken.) 15 THE REPORTER: There's a pending question. 16 Q. I've handed you, sir, what's been marked as 17 Deposition Exhibit 12, which is a series of e-mails 18 between Gary Hansen and -- and Dr. Daniel Sessler. 19 You know who Dr. Sessler is; correct? 20 A. I -- I know the name, yes. 21 Q. And you in fact relied on some of his 22 publications in connection with your opinions in this 23 case; correct? 24 A. Yes, I've cited his work. 25 Q. For example, in your reference list number</p>
<p style="text-align: right;">Page 123</p> <p>1 relied on the ECRI publication as evidence that 2 forced-air warming doesn't increase risk of infection? 3 A. Your -- your question is whether I would 4 have wanted to know because I thought that 3M was 5 manipulating the document or might have been 6 manipulating the document, and I don't know whether 7 that's the case, and I -- 8 Whether it would be interesting to know, 9 it's interesting. 10 Q. I'm just asking you whether it would have 11 been something that you would have wanted to know. 12 A. I -- I don't know. It's all in hindsight. 13 Q. Did you ask 3M for any information related 14 to this ECRI publication? 15 A. No. 16 Q. Were you aware that 3M was refusing to do 17 additional studies into the Bair Hugger? 18 MR. GORDON: Object to the form of the 19 question, also assumes facts not in evidence. 20 A. Would you repeat your question? 21 Q. Sure. Were you aware, prior to the time you 22 issued your opinions in this case, that 3M was 23 refusing to do any additional studies into the Bair 24 Hugger? 25 MR. GORDON: Same objection.</p>	<p style="text-align: right;">Page 125</p> <p>1 three, the Kurz and Sessler, that was one of the 2 references that you relied on; correct? 3 A. That we discussed earlier. 4 Q. Yes. 5 And were you aware that at the time you 6 issued your opinion in this case that Dr. Sessler was 7 an outside science advisor/medical doctor to 3M? 8 A. I was unaware. 9 Q. So you're hearing that today for the first 10 time? 11 A. I think so. 12 Q. Okay. And if we take a look at Borak 13 Exhibit 12, at the bottom it's an e-mail from Dr. 14 Sessler to Gary Hansen at 3M. 15 "Hi Gary, 16 "We were lucky that this was published at 17 almost the same time as Scott's paper. We may not 18 have -- We may not have warning of his next effort 19 though. There is a real possibility that he will do 20 some sort of bacterial sampling study (the idea is 21 obvious) and we'll first know of it in the published 22 paper. If that happens, whatever Scott reports will 23 be un-opposed for one to two years while we do a 24 catch-up study, analysis, and get through the 25 publication process. Waiting much longer seems like a</p>

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<p style="text-align: right;">Page 126</p> <p>1 dangerous strategy."</p> <p>2 Do you see that?</p> <p>3 A. Yes, that's what you read.</p> <p>4 Q. Were you aware that Dan Sessler was urging</p> <p>5 3M for years to do their own bacterial studies?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 A. I -- I -- I don't know that, and that's not</p> <p>9 put forth here.</p> <p>10 Q. Were you aware that -- were you aware that</p> <p>11 Dr. Sessler was urging 3M to do their own bacterial</p> <p>12 studies?</p> <p>13 A. I was not aware.</p> <p>14 (Exhibit 13 was marked for</p> <p>15 identification.)</p> <p>16 BY MS. CONLIN:</p> <p>17 Q. I've handed you, sir, what's been marked as</p> <p>18 Borak Deposition Exhibit 13, which is an e-mail from</p> <p>19 Dan Sessler dated -- looks like approximately a year</p> <p>20 after the e-mail we were just looking at, "Re:</p> <p>21 URGENT!!!!" Do you see that?</p> <p>22 A. I see the top, yes.</p> <p>23 Q. Okay. And it says, "Gary,</p> <p>24 "I'm pretty unhappy. I took this project on</p> <p>25 as a favor and it has ended up costing a huge amount</p>	<p style="text-align: right;">Page 128</p> <p>1 something like that, seven months, eight months, that</p> <p>2 he had been urging that.</p> <p>3 Q. Okay.</p> <p>4 (Exhibit 14 was marked for</p> <p>5 identification.)</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you what's been marked as Borak</p> <p>8 Deposition Exhibit 14. I'm just going to refer you to</p> <p>9 the top part of this e-mail chain from Mark Morton to</p> <p>10 Scott Waite, cc to Michelle Hulse Stevens, Mark Scott</p> <p>11 and Soria Immaculada, and it says --</p> <p>12 And if I could direct your attention in the</p> <p>13 first paragraph where it says "Hi Scott."</p> <p>14 A. I see that.</p> <p>15 Q. Do you see that? Okay. And it said there</p> <p>16 was an inquiry by Dr. Stefan, to which Mr. Morken is</p> <p>17 responding: "Also would really need to understand</p> <p>18 what type of study is being proposed. Given the</p> <p>19 ongoing legal situation, decisions were previously</p> <p>20 made (at a high level) not to pursue clinical research</p> <p>21 on this topic."</p> <p>22 Do you see that?</p> <p>23 A. Bear with me, I --</p> <p>24 Yes.</p> <p>25 Q. Okay. And the subject is "RE: Message to</p>
<p style="text-align: right;">Page 127</p> <p>1 of time -- and now more to come. Furthermore, this</p> <p>2 may damage my reputation; just the fact that a</p> <p>3 complaint was filed already has to some extent."</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And the next paragraph, it says,</p> <p>7 "This was completely preventable. As I've been saying</p> <p>8 for a year, only a bacterial sampling study will</p> <p>9 adequately deal with this issue."</p> <p>10 Do you see that?</p> <p>11 A. I see that.</p> <p>12 Q. Okay. So you have now seen two separate</p> <p>13 e-mails, separate in time, where Dr. Sessler is urging</p> <p>14 3M to do a study; correct?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 A. I -- I'm -- I'm assuming that's what he</p> <p>18 spoke of in the ear -- previous exhibit and his</p> <p>19 concern is reiterated here, but I don't know that to</p> <p>20 be certain.</p> <p>21 Q. If it is, you would agree with me that</p> <p>22 there's at least evidence that over a period of time</p> <p>23 Dr. Sessler was urging 3M to do a study.</p> <p>24 A. Yes. There was apparently evidence that for</p> <p>25 appar -- that at least twice over a period of</p>	<p style="text-align: right;">Page 129</p> <p>1 address safety and efficacy of forced air warming."</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Were you aware that decisions were made at a</p> <p>5 high level at 3M not to do any clinical research into</p> <p>6 the safety and efficacy of their Bair Huggers?</p> <p>7 MR. GORDON: Object to the form of the</p> <p>8 question, mischaracterizes the evidence, --</p> <p>9 A. I had no --</p> <p>10 MR. GORDON: -- assumes facts not in</p> <p>11 evidence.</p> <p>12 A. I had no prior knowledge of that.</p> <p>13 Q. Okay. Was that something that you would</p> <p>14 have thought was important for you to know in</p> <p>15 connection with your opinion that there's a lack of</p> <p>16 evidence showing that the Bair Hugger increases</p> <p>17 infection risk?</p> <p>18 MR. GORDON: Same objection.</p> <p>19 A. It -- it would be interesting to know. But</p> <p>20 as I told you, my opinion rested upon the association</p> <p>21 between the use of Bair Hugger and infections.</p> <p>22 Q. Right. And you -- and you understand, based</p> <p>23 on looking at that, that 3M refused to do further</p> <p>24 research into that topic; correct?</p> <p>25 A. I don't know that that was the topic about</p>

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<p style="text-align: right;">Page 130</p> <p>1 which they refused to do research. There is talk here 2 that says that they decided not to pursue clinical 3 research work on this topic; I am not sure what the 4 topic was. 5 Q. Well read the subject line. 6 A. "Message to address safety and efficacy of 7 forced air warming." I'm sure they were not doing 8 research on the message. And "safety and efficacy" is 9 a very broad and vague area. I don't know what the 10 clinical research was proposed. 11 Q. Well are you aware of any other safety and 12 efficacy issues on the Bair Hugger other than the risk 13 of infection through airborne contamination? 14 MR. GORDON: Object to the form of the 15 question. 16 A. I think that safety and efficacy are two 17 separate issues and I don't know which aspects of 18 either was their concern here. You're asking me to 19 respond to an e-mail which I find unclear. 20 Q. Okay. With respect to the safety of the 21 Bair Hugger, are you aware of any concerns other than 22 the risk of airborne contamination at the time you 23 rendered your opinion in this case? 24 A. I am not specifically aware of any, no. 25 Q. Okay. I may have asked you this before, but</p>	<p style="text-align: right;">Page 132</p> <p>1 others. I don't remember it. 2 Q. My question is a little different. Did 3 you -- 4 Are you rendering an opinion on the efficacy 5 of the Bair Hugger as it relates to maintaining 6 normothermia vis-a-vis any other warming device? 7 A. Ahh. I'm sorry. I misunderstood your 8 question. 9 I was not going to render such an opinion. 10 My understanding is that the -- 11 Q. I just want to know if. 12 A. Okay. 13 Q. If you're not rendering an opinion on it, 14 then that's all I need to know and I'll move on. 15 A. Perfect. Move on. 16 Q. And you didn't do any investigation into 17 that; correct? 18 A. I did not do any investigation into that. 19 Q. I'd like to direct your attention to page 20 six, and I'd like to get an understanding -- 21 Well in paragraph 18 under "Confounding" you 22 say, "Confounding is said to occur when the 23 association between exposure and effect is distorted 24 by some third variable." Okay? 25 Does a confounder have to have association</p>
<p style="text-align: right;">Page 131</p> <p>1 do you believe that The Reference Guide on 2 Epidemiology by Green, Friedman and Gordis is an 3 authoritative work? 4 A. I think it's very good work. I reference 5 it. 6 Q. Okay. And you've never taken any issue with 7 anything that they've said in connection with that 8 reference manual. 9 A. Not that I remember. 10 Q. Did you do -- 11 If we can take a look at page four, footnote 12 one. 13 MR. GORDON: Of his report? 14 MS. CONLIN: Borak Exhibit 1, his expert 15 report. 16 A. Yes. 17 Q. Did you do any investigation into the 18 efficacy of the Bair Hugger vis-a-vis another type of 19 warming device? 20 MR. GORDON: Object to the form of the 21 question. 22 A. I -- I thought that I had read the published 23 literature that might have addressed that. I'm not 24 sure that there was anything other, at the time that I 25 did my report, than McGovern, but there may have been</p>	<p style="text-align: right;">Page 133</p> <p>1 with the effect in order to be a confounder? 2 MR. GORDON: Object to the form of the 3 question. 4 A. I think that some people have written about 5 the ability of things to influence the relationship 6 and to act as an intermediary, but generally I think 7 that a confounder should be associated with both the 8 exposure and the outcome. 9 Q. Okay. There has to be an association. 10 A. I believe so. 11 Q. Okay. And is that the definition that you 12 used in connection with your opinions on the 13 confounding elements that you set forth in your 14 report? 15 A. Yes. 16 Q. All right. I'd like to direct your 17 attention to page 14 of your report and first focus 18 on, starting on paragraph 41, antithrombotic 19 prophylaxis. Okay? 20 A. Yes. 21 Q. Okay. You found that the change in 22 antithrombotic -- thrombotic -- botic prophylaxis, the 23 change from trinzaparin to Xarelto, was a confounder; 24 is that right? 25 A. I think that the use of different</p>

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<p style="text-align: right;">Page 134</p> <p>1 antithrombotic medications confounded the association 2 between warming devices and surgical infections, yes. 3 Q. Well you -- you previously testified that 4 there has to be an association between the potential 5 confounder and the outcome for it to be a confounder; 6 correct? 7 A. Yes. 8 Q. Okay. So there is an association between 9 the antithrombotic prophylaxis and the risk of 10 infection? 11 A. I believe so. 12 Q. Okay. And what do you understand an 13 antithrombotic drug to do? 14 A. Its purpose is to prevent the formation of 15 deep vein thromboses and pulmonary emboli. It 16 essentially down-regulates the clotting system. 17 Q. Okay. And that is there's an association 18 between which drug you use and your chance of 19 infection; correct? 20 MR. GORDON: Object to the form of the 21 question. 22 A. I believe that there is, probably because of 23 the ability of the two drugs to differentially 24 influence bleeding in the wound site. 25 Q. Okay. So what medication you get to avoid</p>	<p style="text-align: right;">Page 136</p> <p>1 infection; correct? 2 A. I said I wasn't aware of evidence that there 3 was an association. That was way back earlier in the 4 deposition. 5 Q. Well I understand, -- 6 A. Okay. 7 Q. -- but I'm just trying to get -- 8 So the -- the use of a drug -- 9 It thins your blood; right? 10 A. Correct. 11 Q. -- can be associated with the risk of 12 infection; correct? 13 A. Yes. 14 Q. But the Bair Hugger is not, based on your 15 opinion. 16 A. The evidence on the antithrom -- 17 I find that you are mingling things and I 18 can't respond "yes" or "no." They are separate. I 19 find that there is insufficient evidence that the Bair 20 Hugger causes infection. I think that there is 21 evidence that the antithrombotic agents can contribute 22 and increase the risk of infection, and I think that 23 the use of the different antithrombotic agents in the 24 context of the McGovern study, in which the two 25 warming devices were used differentially with regards</p>
<p style="text-align: right;">Page 135</p> <p>1 deep vein thrombosis is associated with the risk of 2 infection, in the Bair Hugger it's not; correct? 3 A. I'm sorry, say that again. 4 Q. Well you said there's an association between 5 antithrombotic drugs and your risk of infection; 6 correct? 7 MR. GORDON: Object to the form of the 8 question. 9 A. Yes, ultimately. 10 Q. Okay. So there's an association between 11 that and infection, but not the Bair Hugger and 12 infection; correct? 13 A. The issue concerns the use of different 14 medications differentially with different warming 15 devices, which led to a mixing and confusion of 16 effects. 17 Q. Can you answer my question? 18 A. But your question can't be answered "yes" or 19 "no." I don't think it can be. 20 Q. Well you said there's an infec -- there's an 21 association between antithrombotic prophylaxis drugs 22 and risk of infection; correct? 23 A. Yes. 24 Q. Okay. But there isn't an association 25 between the use of the Bair Hugger and risk of</p>	<p style="text-align: right;">Page 137</p> <p>1 to the thrombotic agents -- antithrombotic agents, may 2 have resulted in the appearance of an association 3 between the warming unit and the risk. 4 Q. Well you find that the switch in 5 antithrombotic agents was a confounder; correct? 6 A. It's not so much the -- the switch, but yes, 7 the thrombotic agents were a confounder. 8 Q. Yes. 9 A. A different confounder. 10 Q. And to be a confounder, there has to be an 11 association. 12 A. Yes. 13 Q. Okay. So how is it that an antithrombotic 14 drug can increase your risk of infection? 15 A. By increasing the risk of bleeding, bleeding 16 being -- the blood being a fantastic culture medium 17 for bacteria and encourages infection. 18 Q. Okay. Did you -- do you have any 19 understanding -- 20 Did you investigate how vascular the joint 21 area is in which a knee or hip implant would be going 22 in? 23 A. I -- I don't think it's necessarily in the 24 joint itself. But I have seen evidence that the use 25 of different medications increases a lot the -- or it</p>

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<p style="text-align: right;">Page 138</p> <p>1 alters a lot the risk of bleeding into the surgery. 2 Q. Okay. And I'm talking about the actual 3 joint. 4 A. I haven't looked into that. 5 Q. Okay. You're aware that the authors of the 6 McGovern study looked at this issue and concluded that 7 they didn't view the change in antithrombotic 8 prophylaxis to be a confounder; correct? 9 MR. GORDON: Object to the form of the 10 question. 11 A. I -- I believe they testified that they 12 thought it was a potential confounder. 13 Q. Do you recall? 14 A. I can read. 15 Q. I'll pull it out for you. 16 A. Both read, -a-d, and -e-d. 17 Q. Well when did you decide that you were going 18 to rely on what the McGovern authors said and how did 19 you go about sorting what you were going to rely upon 20 out of their depositions and what you were going to 21 set aside as not believing? 22 MR. GORDON: I object to the form of the 23 question, assumes facts not in evidence, compound. 24 A. How did I decide? 25 Q. Uh-huh.</p>	<p style="text-align: right;">Page 140</p> <p>1 antithrombotic prophylaxis increases the number of 2 particles over a surgical site during operation? 3 A. I have no knowledge about that. 4 Q. Do you know when an antithrombotic 5 prophylaxis drug is administered in connection with an 6 orthopedic implant? 7 A. My understanding is it's first administered 8 postoperatively. 9 Q. Okay. So it's your opinion that there is an 10 a priori relationship between use of a particular 11 antithrombotic prophylaxis and risk of infection. 12 MR. GORDON: Object to the form of the 13 question. 14 A. I'm not sure what you mean by "an a priori." 15 Q. Do you know what that means, what that term 16 means in connection with an epidemiologic undertaking? 17 A. I -- I have seen it used. I'm interested to 18 know how you're using it in your question. 19 Q. Well how -- how would -- 20 How do you define it? 21 A. As a given. 22 Q. Okay. In connection with your opinions 23 here, when, for example in paragraph 44 -- 24 Well let me -- let me back -- let me ask it 25 more generally.</p>
<p style="text-align: right;">Page 139</p> <p>1 A. I guess I read them and made judgments based 2 upon what I read. 3 Q. Does the use of a thromboprophylactic 4 increase bacteria in a prosthetic joint? 5 A. I've -- 6 There's evidence that use of different 7 antithrombotics can increase the risk of infections in 8 the joint. 9 Q. My question was a little different. 10 A. I understand. I -- I told you earlier I 11 didn't know that much about the blood flow to the 12 joint, but I know there is evidence to sugg -- 13 indicate that there is increased risk of joint 14 infections postoperatively affected by the choice of 15 antithrombotic. 16 Q. Can you answer -- 17 A. That's all that I can opine to. 18 Q. Do you know whether the use of an 19 antithrombotic prophylaxis increases the number of 20 bacteria on a prosthetic joint? 21 A. I don't know that. 22 Q. Okay. That wasn't something that you took 23 into account? 24 A. I wouldn't have taken that into account. 25 Q. Okay. Do you know whether the use of an</p>	<p style="text-align: right;">Page 141</p> <p>1 In connection with your conclusions that 2 there is an association between what antithrombotic 3 prophylaxis drug is used and your risk of infection, 4 were you specifically focused on deep joint infection 5 or SSIs in general? 6 A. I was specifically focused on the McGovern 7 and the Jensen re -- and -- reports, which I 8 understood to be deep joint infections. 9 Q. Okay. Were you the one that suggested that 10 Dr. Holford should reanalyze the McGovern data set 11 using the Jensen report? 12 A. I thought it was very clever but -- and I'd 13 love to take credit for it, but I don't think I was. 14 Q. Okay. And you didn't -- you didn't look at 15 those numbers and see whether they were accurate and 16 you didn't express an opinion on whether that's 17 something that's appropriate to do or not; correct? 18 MR. GORDON: Object to the form of the 19 question. 20 A. I -- I think when I first read it -- 21 You're asking me whether I suggested it. 22 I'm not sure that I suggested it. I know that I 23 remarked to myself and to no one else that the Jensen 24 report had a shorter followup and that the 25 postoperative joint infections could be delayed and</p>

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<p style="text-align: right;">Page 142</p> <p>1 therefore the Jensen report might have undercounted</p> <p>2 infections. I did not look to see the numbers of</p> <p>3 cases which suggest that the Jensen report included</p> <p>4 other kinds of cases other than those included in</p> <p>5 McGovern.</p> <p>6 Q. You didn't express an opinion on whether</p> <p>7 what Professor Holford did in connection with his</p> <p>8 remix or reanalysis of the McGovern data set taking</p> <p>9 into account Jensen was appropriate; correct?</p> <p>10 A. Did I express an opinion?</p> <p>11 Q. Yes.</p> <p>12 A. In my writing I think I -- I accepted Dr.</p> <p>13 Holford's reanalysis.</p> <p>14 (Discussion off the stenographic record.)</p> <p>15 Q. Okay. Now you un --</p> <p>16 You understand that after McGovern, Dr. Reed</p> <p>17 published another study analyzing wound complications</p> <p>18 following the use of Xarelto.</p> <p>19 A. I -- I -- I'm not surprised when you say it,</p> <p>20 but I can't think of it right off the top. Can you</p> <p>21 give me a title?</p> <p>22 Q. Not right now, but I -- I'll pull it out for</p> <p>23 you in a second.</p> <p>24 A. Okay.</p> <p>25 Q. You're aware that Dr. Reed testified that,</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. What do you --</p> <p>2 Explain to me the mechanism by which the use</p> <p>3 of Xarelto increases your infection risk over</p> <p>4 trinzaparin.</p> <p>5 A. My understanding is it increases bleeding</p> <p>6 into the wound, and that the blood in the wound is a</p> <p>7 great culture medium and accelerates and enhances</p> <p>8 infection.</p> <p>9 Q. Well both are antithrombotic; correct?</p> <p>10 A. Correct, but by different mechanisms.</p> <p>11 Q. So --</p> <p>12 A. And my understanding is that there is a</p> <p>13 differential in the rate of postoperative bleeds when</p> <p>14 rivaroxaban was used.</p> <p>15 Q. Well rivaroxaban is Xarelto; correct?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And what's that based on?</p> <p>18 A. The literature that I have reviewed. It's</p> <p>19 clearly in the Jensen paper, it's probably in others,</p> <p>20 but I -- I can't make this a memory test and I</p> <p>21 apologize. But Jensen certainly indicates increased</p> <p>22 risks with rivaroxaban.</p> <p>23 Q. We'll get to Jensen in a second. I'm just</p> <p>24 asking you if you understand the mechanism by which</p> <p>25 you think that use of trinzaparin creates a lower risk</p>
<p style="text-align: right;">Page 143</p> <p>1 based on the results of that study, that, quote, "We</p> <p>2 can now exclude Xarelto as a confounding factor for</p> <p>3 infection rate." You're aware of that; correct?</p> <p>4 A. I'm sorry, I don't remember the statement.</p> <p>5 Q. Okay. Was that something that would be</p> <p>6 important to you, that the author of the McGovern</p> <p>7 study did further work into the -- the use of Xarelto</p> <p>8 as an antithrombotic prophylaxis and found that -- he</p> <p>9 said that it could be excluded as a confounding factor</p> <p>10 for infection rates?</p> <p>11 A. I -- I would certainly want to see it before</p> <p>12 I rendered any opinion about it.</p> <p>13 Q. Are you aware that Professor Nachtsheim</p> <p>14 said the same thing?</p> <p>15 A. I don't remember that particularly.</p> <p>16 Q. And you didn't even cite that article in</p> <p>17 your report; did you, sir?</p> <p>18 A. I don't think I did, no.</p> <p>19 Q. Okay. So how is it that --</p> <p>20 MR. GORDON: What -- what article are you</p> <p>21 referring to?</p> <p>22 MS. CONLIN: The Reed article on Xarelto.</p> <p>23 MR. GORDON: Is he the first -- first --</p> <p>24 Q. What do you -- what do --</p> <p>25 MR. GORDON: Is he the first author?</p>	<p style="text-align: right;">Page 145</p> <p>1 for infection than Xarelto.</p> <p>2 A. I understand that tinza -- tinzap --</p> <p>3 trinzaparin -- I don't know how to say it, but I</p> <p>4 believe it's trinzaparin -- I believe that it is</p> <p>5 associated with less wound bleeding postoperatively.</p> <p>6 Q. We'll just go there. Hold on.</p> <p>7 (Exhibit 15 was marked for</p> <p>8 identification.)</p> <p>9 THE WITNESS: Thank you.</p> <p>10 BY MS. CONLIN:</p> <p>11 Q. I've handed you what's been marked as Borak</p> <p>12 Deposition Exhibit 15, which is an article entitled</p> <p>13 "Return to the surgery following total hip and knee</p> <p>14 replacement, before and after the introduction of</p> <p>15 rivaroxaban." Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. And the rivaroxaban is Xarelto; correct?</p> <p>18 A. I believe so.</p> <p>19 Q. Okay. And is this the study that you're</p> <p>20 referencing?</p> <p>21 A. I believe it is. I've looked at it in a</p> <p>22 different format, so it's --</p> <p>23 It was a pdf, printed in a different format,</p> <p>24 but I think it's correct.</p> <p>25 Q. Okay. Do you see the third author listed</p>

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<p style="text-align: right;">Page 146</p> <p>1 there?</p> <p>2 A. Is it Partington?</p> <p>3 Q. No, that would be the -- well do you see --</p> <p>4 I guess it would be the fourth then. Do you</p> <p>5 see the fourth author there?</p> <p>6 A. Dr. Reed.</p> <p>7 Q. Okay. Are you aware that Dr. Reed testified</p> <p>8 that this study showed no --</p> <p>9 Well strike it. Let me ask it a different</p> <p>10 way.</p> <p>11 Are you aware that Dr. Reed testified that</p> <p>12 this study eliminates Xarelto as a confounder for</p> <p>13 infection risks in knee and hip surgeries?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. I'm --</p> <p>17 I don't remember that he said that, but I</p> <p>18 think it's wrong.</p> <p>19 Q. Okay. So you don't remember reading it, but</p> <p>20 if he said it, he's wrong.</p> <p>21 A. I believe it does not eliminate it. Yes,</p> <p>22 that's correct.</p> <p>23 Q. Okay. And he's somebody who has</p> <p>24 investigated this issue. You're somebody who has read</p> <p>25 some articles. Correct?</p>	<p style="text-align: right;">Page 148</p> <p>1 A. Did he say that here?</p> <p>2 Q. He said it in his deposition. I'm</p> <p>3 representing that to you.</p> <p>4 A. I -- I don't think that this study</p> <p>5 eliminates rivaroxaban as a confounder in the McGowan</p> <p>6 study.</p> <p>7 Q. Okay. Based on what is my question.</p> <p>8 A. Based on the fact that there was a</p> <p>9 significant increase -- there was a large increase, I</p> <p>10 think 2.5-to-one increase in infection rates, and I</p> <p>11 think this study under-ascertained cases because it</p> <p>12 only had a 30-day followup.</p> <p>13 Q. Well so you relied on it but you didn't rely</p> <p>14 on it?</p> <p>15 A. No, no, no, no, no. I didn't rely upon it.</p> <p>16 I said I think it did not prove that it was not a</p> <p>17 confounder. Moreover, a confounder -- whether</p> <p>18 something is or is not a confounder is not dependent</p> <p>19 on whether it is, on a univariate level, statistically</p> <p>20 significantly associated with the outcome or whether</p> <p>21 it significantly influences the relationship that it</p> <p>22 confounds.</p> <p>23 Q. It has to have an association.</p> <p>24 A. That's a start but not a finish.</p> <p>25 MS. CONLIN: Okay. So why don't you pull</p>
<p style="text-align: right;">Page 147</p> <p>1 MR. GORDON: Object to the form of the</p> <p>2 question.</p> <p>3 Q. You haven't done an investigation beyond</p> <p>4 what you -- what you've read; correct?</p> <p>5 A. I have not directly studied the use of</p> <p>6 Xarox -- Xarelto.</p> <p>7 Q. Okay. What investigation did you do other</p> <p>8 than read the couple of articles that are cited in</p> <p>9 your report?</p> <p>10 A. Well I've read a lot of articles. Only</p> <p>11 those cited are the ones I specifically was relying</p> <p>12 upon. I don't want to diminish the effort that was</p> <p>13 put into it, but I read the literature.</p> <p>14 Q. Okay. With respect to this issue of Xarelto</p> <p>15 being a potential confounder --</p> <p>16 A. Yes.</p> <p>17 Q. -- for the risk of infection in knee and hip</p> <p>18 surgeries, what other articles do you have in mind</p> <p>19 other than those that you cited in your report?</p> <p>20 A. I think at the moment those are the ones</p> <p>21 specifically that I would name.</p> <p>22 Q. And to the extent that Dr. Reed, an author</p> <p>23 of this study, said that this study proves that</p> <p>24 Xarelto is not a confounder in knee and hip surgery,</p> <p>25 you would disagree with him.</p>	<p style="text-align: right;">Page 149</p> <p>1 out, Mr. Stirewalt, what was marked yesterday as</p> <p>2 Exhibit 19, because I think that is probably the pdf</p> <p>3 that he's used to seeing in connection with this</p> <p>4 study.</p> <p>5 A. Maybe that one.</p> <p>6 (Holford Exhibit 19 handed to the witness.)</p> <p>7 Q. I've handed you what's previously been</p> <p>8 marked as Holford Exhibit 19, which is, I believe, the</p> <p>9 same study in a different format. Is this the format</p> <p>10 that you're used to seeing this study?</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. Okay. And did you understand this study to</p> <p>13 be breaking down wound complications such as surgical</p> <p>14 wound infections versus deep joint infections?</p> <p>15 MR. GORDON: Object to the form of the</p> <p>16 question.</p> <p>17 A. You're asking me whether it specifically</p> <p>18 differentiated different kinds of wound infections?</p> <p>19 Q. Deep joint versus a superficial wound</p> <p>20 infection or the like. Did you have that in mind when</p> <p>21 you reviewed this?</p> <p>22 A. I don't recall having that particular</p> <p>23 question in mind, --</p> <p>24 Q. Okay.</p> <p>25 A. -- but I will -- would again if you'd like</p>

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<p style="text-align: right;">Page 150</p> <p>1 me to.</p> <p>2 Q. Did you have it in mind when you rendered</p> <p>3 your opinions in this case on June 2nd?</p> <p>4 A. Whether --</p> <p>5 The differentiation between the types of</p> <p>6 wound infections?</p> <p>7 Q. Correct.</p> <p>8 A. I -- I'm sorry, and I'm just backing up. Is</p> <p>9 that raised in this document? It would help me to</p> <p>10 reconstruct and answer your question.</p> <p>11 Q. Well I'm just asking if you had it in mind</p> <p>12 when you --</p> <p>13 A. I'm sure I had it somewhere in mind, but I</p> <p>14 don't remember whether it was relevant, that question,</p> <p>15 to this article.</p> <p>16 Q. Okay. Why don't you take a look at</p> <p>17 intern -- page 523, which is the third page of this</p> <p>18 study, under "Results," and I'd like to direct your</p> <p>19 attention down to the third paragraph starting with</p> <p>20 "Of those patients who returned to theatre,</p> <p>21 microbiology results showed that five of the nine</p> <p>22 (55.5 percent) in group 1 had a deep infection,</p> <p>23 compared with 14 of 22 (63.6 percent) in group 2."</p> <p>24 A. Okay.</p> <p>25 Q. And it's got a p-value of .7, do you see</p>	<p style="text-align: right;">Page 152</p> <p>1 A. It's discussed in paragraph 42 and following</p> <p>2 in my report.</p> <p>3 Q. My question is a little different. Did you</p> <p>4 take that into account in connection with your</p> <p>5 conclusions in this case?</p> <p>6 A. And I'm showing you, yes, I took it into</p> <p>7 account --</p> <p>8 Q. Okay.</p> <p>9 A. -- in paragraphs 42 and following in my</p> <p>10 report.</p> <p>11 Q. I think I asked you this before, but in</p> <p>12 connection -- you didn't --</p> <p>13 You didn't actually look at the mathematical</p> <p>14 work Professor Holford did in reanalyzing the McGovern</p> <p>15 data with Jensen; correct?</p> <p>16 MR. GORDON: Objection.</p> <p>17 A. Yes, I did not.</p> <p>18 Q. Okay. And to the extent that he used either</p> <p>19 data from Albrecht Exhibit 10 or McGovern Exhibit 16,</p> <p>20 you would be deferring to him as to the</p> <p>21 appropriateness of that; correct?</p> <p>22 A. Yes, I would.</p> <p>23 Q. Now I'd like to talk to you a little bit</p> <p>24 about the Hawthorne effect and -- which is contained</p> <p>25 on page 16 of your report. Wouldn't --</p>
<p style="text-align: right;">Page 151</p> <p>1 that?</p> <p>2 A. I'm sorry, let me try and read it more</p> <p>3 clearly. I'm not seeing it well enough in this print.</p> <p>4 Yes. Okay, I see that.</p> <p>5 Q. Okay. And do you see the p-value of .7?</p> <p>6 A. .7 had to do with the probability that there</p> <p>7 was a difference in the rate of deep versus</p> <p>8 superficial infections.</p> <p>9 Q. My question is: Do you see the p-value of</p> <p>10 .7?</p> <p>11 A. Yes, I see it.</p> <p>12 Q. Is that statistically significant?</p> <p>13 A. No.</p> <p>14 Q. Okay. Then it says, "The overall rate of</p> <p>15 deep infection in group 1 was 1 percent (95) compared</p> <p>16 with 2.5 percent in group 2," p-value of .102, do you</p> <p>17 see that?</p> <p>18 A. I do.</p> <p>19 Q. Is that statistically significant?</p> <p>20 A. It is not.</p> <p>21 Q. Did you take that into account in connection</p> <p>22 with your conclusions in this case that Xarelto is a</p> <p>23 confounding factor for risk of infection?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 153</p> <p>1 Well first of all, wouldn't the Hawthorne</p> <p>2 effect exist in any observational study?</p> <p>3 A. I think it depends upon whether the subjects</p> <p>4 are aware of the observation and how intensively the</p> <p>5 observation impacts the daily life of those</p> <p>6 individuals.</p> <p>7 Q. Well do you know whether any of the</p> <p>8 participants in the Reed and McGovern study were</p> <p>9 involved, that there was a study going on?</p> <p>10 A. I -- I understand from the statements that</p> <p>11 were made in the citation which I cited -- "citation</p> <p>12 which I cited" sounds like a redundancy -- there was</p> <p>13 an award given to Northumbria, and in the context of</p> <p>14 that they cited the efforts that had gone into it.</p> <p>15 There's also description of the change in the</p> <p>16 sensibility that was engendered as described by</p> <p>17 Gillson and Lowdon or something, and my understanding</p> <p>18 is that there was a full-court press to try to change</p> <p>19 the behavior of the people, which included changing</p> <p>20 clothes and changing the manner in which the clothes</p> <p>21 were stored and changing shoes, and a variety of other</p> <p>22 things were done, and I think that everybody there was</p> <p>23 very aware that there was a problem with infections.</p> <p>24 Q. My question was a little different.</p> <p>25 A. Okay. I'm sorry.</p>

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<p style="text-align: right;">Page 154</p> <p>1 Q. My question was: Do you believe that any of 2 the participants' employees understood or were aware 3 that there was going to be an observational study 4 conducted and published regarding infections in knee 5 and hip arthroplasty? 6 A. I -- I have -- 7 MR. GORDON: Object to the form of the 8 question. 9 A. I have no idea if anybody at the time knew 10 because the study was post hoc. 11 (Discussion off the stenographic record.) 12 (Exhibit 16 was marked for 13 identification.) 14 THE WITNESS: Thank you. 15 BY MS. CONLIN: 16 Q. I have handed you, sir, what's been marked 17 as Borak Deposition Exhibit 16, which is -- not what I 18 wanted to give you. Hold on. You can set that aside, 19 I'll get back to that. 20 (Exhibit 17 was marked for 21 identification.) 22 BY MS. CONLIN: 23 Q. I have handed you, sir, what's been marked 24 as Borak Deposition Exhibit 17, -- 25 A. Yes.</p>	<p style="text-align: right;">Page 156</p> <p>1 Would you point to what you are talking 2 about in the paper so I understand the context of your 3 question? 4 Q. Well I'm just under -- 5 I'm trying to understand your opinion, sir, 6 when you say that the change in -- from rivar -- or 7 from trinzaparin to Xarelto creates an increased risk 8 of a deep joint infection, that you had paid attention 9 in the papers that you were citing as to differences 10 between, for example, a superficial wound or a deep 11 wound infection and a deep joint infection. 12 A. I'm sorry, I -- I cited this paper for a 13 different reason, not to suggest what you are asking. 14 I cited it because Dr. Samet had cited it, and Dr. 15 Samet had cited it as evidence that it did not create 16 a difference. 17 Q. My question was: When you opine that a 18 change from trinzaparin to Xarelto creates an 19 increased risk of deep joint infection, did you pay 20 attention in the papers that you were citing as to the 21 differences between, for example, superficial wound or 22 deep wound or a deep joint infection? 23 A. Let me answer, yes, I was aware of the 24 difference. 25 Q. Do you think that you can extrapolate from</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. -- which is the Jameson study entitled 2 "Wound Complications Following Rivaroxaban 3 Administration." This is one of the documents that 4 you referenced and opined on in your report; correct? 5 A. That's correct. 6 Q. Okay. In connection with your review, did 7 you have in mind a difference or -- between a deep 8 joint infection and a superficial or deep tissue 9 infection? 10 A. I don't think it was defined clearly in this 11 paper, and so I don't think that I made a decision. 12 But -- 13 Q. Okay. Would it be important in connection 14 with making decisions that a change to Xarelto 15 postoperatively as an antithrombotic prophylaxis 16 increases the risk of a deep joint infection? 17 A. I'm sorry, repeat that. 18 Q. Sure. Would it be important in connection 19 with making decisions in this case that a change in 20 Xarelto postoperatively -- postoperatively as an 21 antithrombotic prophylaxis increases the risk of a 22 deep joint infection as opposed to another kind of 23 wound infection? 24 A. Would it matter to me? Yes, I would 25 consider that. I --</p>	<p style="text-align: right;">Page 157</p> <p>1 papers regarding superficial wound infections to a 2 deep joint infection? 3 A. I am not a nosocomial infection expert. I 4 was looking at a very specific paper, not generalizing 5 from it. It was a paper that was cited for a 6 particular purpose. I was responding to that. 7 Q. Can you answer my question? 8 A. Ask the question again. 9 Q. Sure. Do you think that you can extrapolate 10 from papers regarding superficial wound infections to 11 deep joint infections in connection with what might be 12 a confounder or not? 13 A. I -- I didn't. I'm not sure that I did that 14 and I'm not sure that you can do that. 15 Q. Okay. You'd agree with me that there's a 16 difference between a -- a -- a superficial surgical- 17 site infection and a deep joint infection; correct? 18 A. I understand that there is a difference. 19 Q. Okay. Changing the dressings or a change in 20 protocol on changing the dressings might affect a 21 superficial surgical-site infection but not 22 necessarily impact a deep joint infection. 23 A. Or might affect both, yes. 24 Q. Do you know whether it could affect both? 25 A. I thought I had seen comments by Dr. Reed</p>

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<p style="text-align: right;">Page 158</p> <p>1 indicating that a change in dressing affected that 2 outcome, but I can't point to where it was other than 3 maybe a deposition. 4 Q. So it's your understanding that Dr. Reed 5 said that a change in dressing or change in protocol 6 in dressings could affect a deep joint infection? 7 A. I believe that is my remembrance, but it may 8 not be correct. I didn't focus on it. 9 Q. Well you talked about changes in the 10 protocol; right? 11 A. Yes. 12 Q. And skin preparation; right? 13 A. Yes. 14 Q. Okay. Do you think that a change in skin 15 preparation can have an impact on a deep joint 16 infection? 17 A. Absolutely. 18 Q. Okay. How so? 19 A. Reducing the number of bacteria on the skin 20 reduces the likelihood of followup -- of -- of 21 infection postoperatively. 22 Q. Okay. So having less bacteria on your skin 23 can lower your risk of a deep joint infection. 24 A. I think there's evidence of that. 25 Q. Okay. But you don't know whether having an</p>	<p style="text-align: right;">Page 160</p> <p>1 AFTERNOON SESSION 2 BY MS. CONLIN: 3 Q. If the change in antithrombotic prophylaxis 4 is not a confounder, in other words, meaning there's 5 no association as -- as you've described it, doing a 6 remix of the Jensen data and the McGovern data would 7 not make sense in that case; right? 8 MR. GORDON: Object to the form of the 9 question. 10 A. You asked me first a hypothetical, saying if 11 there were none. 12 Q. Yup. 13 A. Okay. And then when you say the remix, are 14 you referring to what Professor Holford did? 15 Q. Correct. 16 A. I think that it would still have merit given 17 the fact that the followup period in the Jensen study 18 was probably too short because of the well-recognized 19 delay in the manifestation of infections. 20 Q. The hypothetical is is that the change in -- 21 there's no association between a change in 22 antithrombotic prophylaxis and infection. If that's 23 the case, there would be no reason for Dr. Holford to 24 attempt to remix the data from Jensen; correct? 25 A. Correct, other than to question whether that</p>
<p style="text-align: right;">Page 159</p> <p>1 increase in infectious microbes in the air can affect 2 your ability to get a deep joint infection; correct? 3 A. I said I don't -- I don't have an opinion 4 about that. 5 Q. Okay. 6 A. That's correct. 7 Q. So if it's on the skin, you have an opinion 8 about it, if it's in the air, you don't; correct? 9 A. The answer is yes, because the available 10 data are different. 11 MS. CONLIN: Okay. All right. Why don't we 12 stop here for lunch. 13 THE REPORTER: Off the record, please. 14 (Luncheon recess taken.) 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 161</p> <p>1 assumption was correct or incorrect. 2 (Exhibit 18 was marked for 3 identification.) 4 BY MS. CONLIN: 5 Q. I've handed you what's been marked as Borak 6 Exhibit 18, which was -- is an excerpt from the 7 deposition of Dr. Reed, and I'd like to direct your 8 attention to internal page 215 of this exhibit. And 9 this is relating to the Reed study, I'll represent to 10 you, the Reed study on Xarelto that we just looked at 11 and was marked as Exhibit 19. If we can take a look 12 at page 215 -- 13 Let me -- let me just make sure I gave you 14 the right exhibit number. Yeah, that's it. 15 A. Can -- can we, just for avoiding confusion, 16 agree that what you were referring to as the Reed 17 study is the Jensen study? 18 Q. Sure. And I apologize for that. 19 A. No, no, no, no, no. I -- I'm not trying to 20 make it harder, -- 21 Q. All right. 22 A. -- I'm trying to make it clearer. 23 Q. So with regard to this testimony on page 24 215, internal page 215 of Exhibit 18, they're 25 referencing the Jensen study, and I'd like to direct</p>

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<p style="text-align: right;">Page 162</p> <p>1 your attention down to line --</p> <p>2 MR. GORDON: Jan, I -- I -- I can't believe</p> <p>3 you're trying to sandbag him with that. He's not</p> <p>4 talking about the Jensen study here. And I -- I --</p> <p>5 I'm assuming you don't know. He's talking about the</p> <p>6 Jameson study.</p> <p>7 MS. CONLIN: Oh, okay. I stand corrected.</p> <p>8 As you know me, Mr. Gordon, I wouldn't do that to a</p> <p>9 witness, so --</p> <p>10 MR. GORDON: And that's why I said it that</p> <p>11 way.</p> <p>12 MS. CONLIN: All right. Thank you. Yeah.</p> <p>13 Okay.</p> <p>14 Q. Do you see the testimony on 215, starting at</p> <p>15 line 14 --</p> <p>16 And I stand corrected. It is in connection</p> <p>17 with the Jameson study which is -- we also marked this</p> <p>18 morning as Exhibit 17.</p> <p>19 MR. GORDON: Seventeen.</p> <p>20 Q. Okay? And do you see it says:</p> <p>21 "So based on this study of 12,000 patients,</p> <p>22 I would say that there was no effect on return to</p> <p>23 surgery from infection.</p> <p>24 "Question: So would you agree with me that</p> <p>25 based on this study, that you are an author of, and</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Yes.</p> <p>2 Q. And you disagree with his conclusions as it</p> <p>3 relates to the Jensen study, of which he is also an</p> <p>4 author; correct?</p> <p>5 A. We -- I --</p> <p>6 I think so, but I'm not sure which</p> <p>7 conclusion you're referring to.</p> <p>8 Q. That Xarelto was not a confounding factor in</p> <p>9 connection with the McGovern study.</p> <p>10 A. It's two separate issues. I agree with you</p> <p>11 on both of those. I disagree with Dr. Reed.</p> <p>12 Q. Okay.</p> <p>13 A. You're not interested in why?</p> <p>14 Q. Actually, I am. Go ahead and tell me why</p> <p>15 you disagree.</p> <p>16 A. Well I think that in the Jensen study the</p> <p>17 2.5-to-one ratio of deep infection increase is</p> <p>18 indication of confounding. The only conclusion that</p> <p>19 supports that it's not important is that it's</p> <p>20 statistically not significant, and when re-evaluated</p> <p>21 it was statistically significant. That is Dr.</p> <p>22 Holford's re-evaluation.</p> <p>23 The Jameson study provides a totally</p> <p>24 different thing. It contains contradictory internal</p> <p>25 information that I believe it is not useful, and part</p>
<p style="text-align: right;">Page 163</p> <p>1 looking at the date of the McGovern paper, that we can</p> <p>2 exclude xarelto as a confounding factor for infection</p> <p>3 rates?"</p> <p>4 MS. CONLIN: He's not an author on that, Mr.</p> <p>5 Gordon.</p> <p>6 THE WITNESS: Mr. -- Dr. Reed is.</p> <p>7 MS. CONLIN: On the Jameson paper?</p> <p>8 MR. GORDON: Yes.</p> <p>9 THE WITNESS: He's the last author.</p> <p>10 MS. CONLIN: Okay.</p> <p>11 MR. GORDON: He's a senior author.</p> <p>12 Q. Okay. So let me start over. With reference</p> <p>13 to the Jameson paper, the testimony went as follows:</p> <p>14 "So would you agree with me that based on</p> <p>15 this study, that you are an author of, that looking at</p> <p>16 the date of the McGovern paper, that we can now</p> <p>17 exclude xarelto as a confounding factor for infection</p> <p>18 rates?</p> <p>19 "Answer: I think that's what this paper</p> <p>20 says."</p> <p>21 Do you see that?</p> <p>22 A. I do see that.</p> <p>23 Q. And you disagree with Dr. Reed, the author</p> <p>24 of the Jameson -- one of the authors of the Jameson</p> <p>25 study; correct?</p>	<p style="text-align: right;">Page 165</p> <p>1 of it is that while it does at one place say that the</p> <p>2 combined data did not have a statistically significant</p> <p>3 increase -- and that's in a table on page 1556 --</p> <p>4 however, there were these other difficulties. One of</p> <p>5 them is that the numbers don't add up. It -- it does</p> <p>6 not make sense, the paper, the data do not make sense.</p> <p>7 And the other is that the authors clearly state that</p> <p>8 they were unable to differentiate from this pooled</p> <p>9 data set between return to theater for infection</p> <p>10 versus return for other wound complications, and they</p> <p>11 just pooled them.</p> <p>12 Now the point I made in my report -- and I</p> <p>13 just point out so you understand -- I'm -- what I'm</p> <p>14 saying is the Jameson study isn't usable, and I point</p> <p>15 to the fact that in Table 2 on what you refer to as</p> <p>16 internal 1556, there is a count of total wound</p> <p>17 complications and underneath that there is a list of</p> <p>18 those that were managed non-operatively and those that</p> <p>19 returned to surgery for infection, and when you add</p> <p>20 them up, it does not square. There are too many</p> <p>21 cases. The numbers are not correct.</p> <p>22 Q. Okay. So that's based on your view that you</p> <p>23 couldn't understand what was going on in that study,</p> <p>24 but you don't agree with the author of the study who</p> <p>25 says in his mind this created a conclusion that</p>

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<p style="text-align: right;">Page 166</p> <p>1 Xarelto was not a confounding factor in McGovern. 2 A. Yes, I believe these data did not support 3 that conclusion. 4 Q. Now you mentioned in that last answer that 5 you thought the authors didn't discriminate between 6 re -- repeat surgical-wound irrigation for infection 7 and surgery for hematoma; correct? 8 A. Yes. 9 Q. That -- that involves the procedure, not the 10 detection of a DJI; correct? 11 A. They group them together. 12 Q. Well no. It just -- 13 They grouped them together for the purposes 14 of the surgery, not whether there were infections. 15 A. Yes, yes, yes. 16 Q. Okay. 17 A. And there's no data to conclude about 18 infections because they were grouped together. They 19 do not have a separate list. To the contrary, what 20 they say was -- if I can find it -- 21 I'm sorry, let me -- I have it in my report. 22 If I find it, it will save rather than looking in -- 23 Q. I read it in your report. Let's move on. 24 A. Okay. 25 Q. If we can direct your attention to page 14</p>	<p style="text-align: right;">Page 168</p> <p>1 protocol and the risk of infection, at least as it 2 relates to skin preparation; correct? 3 A. I -- I think that that is correct. 4 Q. Okay. And in connection with this you cite 5 Dr. Reed's testimony; right? Quote, "If your surgeon 6 is still using iodine plus alcohol then there is a 7 very robust study that shows they could do better;" 8 correct? 9 A. Correct, I did cite that. 10 Q. So in connection with this you're relying on 11 Dr. Reed; correct? 12 A. I'm pointing to Dr. Reed agreeing with me, 13 yes. 14 Q. Right. You're relying on it. 15 A. I don't know that I specifically relied upon 16 it, but I cited it. 17 Q. Well you said earlier in your report that if 18 you cited it, you relied on it. 19 A. No, no. I appreciate what you're saying. I 20 would have reached the same conclusion without Dr. 21 Reed's opinion. 22 Q. Okay. But you took the time to put Dr. 23 Reed's testimony in on this; correct? 24 A. I did. 25 Q. Okay. And then you say, "Use of</p>
<p style="text-align: right;">Page 167</p> <p>1 of your report, -- 2 A. Yes. 3 Q. -- and I'd like to talk to you about your 4 section entitled "...Skin Preparation." 5 A. Yes. 6 Q. Okay. And it's your opinion that the -- 7 Is it your opinion that the change in skin 8 preparation protocol during the McGovern study period 9 was a confounder? 10 A. It probably was. There's no evidence to say 11 "yes" or "no," but it is one that should have been 12 considered. I think it was likely to be. 13 Q. Okay. So without evidence, you're okay 14 saying there is an association between the change in 15 skin protocol and the risk of infection, is that 16 right, at least as it relates to skin preparation? 17 A. My sen -- my -- 18 My statement was to the extent that use of 19 chlorhexidine reduced infections would be -- only 20 reduce the rate in the non-FAW cases, thereby wrongly 21 suggesting a benefit. In that case, it would have 22 been a confounder. 23 Q. My -- my question was -- okay. 24 My question was: So you're saying that 25 there's an association between the change in skin</p>	<p style="text-align: right;">Page 169</p> <p>1 chlorhexidine alcohol has been reported to reduce SSI 2 by up to 40 percent compared to po -- povidone- 3 iodine" -- 4 Did I say that right? 5 A. No, but it's close enough. 6 Q. How do you say that? 7 A. Povidone. 8 Q. Povidone-iodine. 9 A. Povidone. 10 Q. Povidone. 11 A. I actually normally put a -- incorrectly put 12 an "r" in the word. That's okay, I will take however 13 you say it. 14 Q. -- "povidone-iodine and it reduced 15 infections related to vascular catheters by 49 16 percent." Correct? 17 A. Correct. 18 Q. That didn't involve deep joint infections, 19 correct, -- 20 A. No, it did not. 21 Q. -- in arthroplastic or hip -- hip and knee 22 replacements; correct? 23 A. Correct. 24 Q. And you also cite in that sentence to 25 reference 33, which is a Darouiche reference; correct?</p>

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<p style="text-align: right;">Page 170</p> <p>1 A. Correct.</p> <p>2 Q. Let me pull that out for you.</p> <p>3 (Exhibit 19 was marked for</p> <p>4 identification.)</p> <p>5 THE WITNESS: Thank you.</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you, sir, what's been marked as</p> <p>8 Deposition Exhibit 19, which is an article entitled</p> <p>9 "Chlorhexidine-Alcohol versus Povidone-Iodine for</p> <p>10 Surgical-Site Antisepsis." Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. And the lead author on this is Dr.</p> <p>13 Darouiche; --</p> <p>14 A. Correct.</p> <p>15 Q. -- correct? And I'd like --</p> <p>16 And this was something you relied on to say</p> <p>17 that the change in skin preparation during the</p> <p>18 McGovern period was a confounder; correct?</p> <p>19 A. Correct.</p> <p>20 Q. So let's take a look at the results section</p> <p>21 on this. It says about midway down, "Chlorhexidine-</p> <p>22 alcohol was significantly more protective than</p> <p>23 povidone-iodine against both superficial incisional</p> <p>24 infections and deep incisional infections" --</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 172</p> <p>1 A. I said it decreases deep infections, and I</p> <p>2 believe that's a risk for joint infections. But I</p> <p>3 would defer on that opinion probably to Dr. Wenzel.</p> <p>4 Q. How -- how does a microbe from the skin get</p> <p>5 onto an implant?</p> <p>6 A. It depends on the circumstance. I think</p> <p>7 that, for example, it can swim through the tissues.</p> <p>8 Q. So it starts on the skin and decides it</p> <p>9 wants to land on the implant and it swims down?</p> <p>10 A. I don't know whether it makes a conscious</p> <p>11 decision, but I think that there is a spread that can</p> <p>12 occur, yes.</p> <p>13 Q. Okay. But you don't think that it can be</p> <p>14 floating in the air and drop down, it's got to swim</p> <p>15 through the tissue?</p> <p>16 A. I don't know that. I've said only that I</p> <p>17 see no evidence that the air dispersion results in</p> <p>18 increased infections.</p> <p>19 Q. Okay. And in your mind there is -- that</p> <p>20 if -- that if something decreases a deep tissue</p> <p>21 infection, it should also decrease the risk of a deep</p> <p>22 joint infection?</p> <p>23 A. I think it's reasonable to me, but it's not</p> <p>24 my area of expertise and it's not an expert opinion</p> <p>25 that I'm rendering.</p>
<p style="text-align: right;">Page 171</p> <p>1 A. I do.</p> <p>2 Q. It says:</p> <p>3 -- "but not against organ-space infections."</p> <p>4 Do you see that?</p> <p>5 A. I do.</p> <p>6 Q. 4.4 percent to 4.5 percent; correct?</p> <p>7 A. Correct.</p> <p>8 Q. Okay. So how is it that this study supports</p> <p>9 your conclusion that the change in skin preparation</p> <p>10 during the McGovern period was a confounder?</p> <p>11 A. I think it provides evidence of decreased</p> <p>12 wound infections, and I believe wound infections lead</p> <p>13 to, mechanistically, deep infections and conceivably</p> <p>14 joint infections.</p> <p>15 Q. How did you rely on this study when the</p> <p>16 authors found virtually no change in deep joint</p> <p>17 infections --</p> <p>18 MR. GORDON: Object to the form --</p> <p>19 Q. -- between the two protocols?</p> <p>20 MR. GORDON: Object to the form,</p> <p>21 mischaracterizes the evidence.</p> <p>22 A. It provides evidence of decreased deep wound</p> <p>23 infections. I believe that is a risk for the joint</p> <p>24 infections.</p> <p>25 Q. I'm sorry, can you say what you said again?</p>	<p style="text-align: right;">Page 173</p> <p>1 Q. Okay. Well you'd agree with me that looking</p> <p>2 at the Darouiche article suggests that there is no</p> <p>3 difference for deep joint infections between these two</p> <p>4 protocols.</p> <p>5 MR. GORDON: Jan, again I'm going to assume</p> <p>6 you're -- you're -- you're -- you're not doing this</p> <p>7 intentionally. Darouiche says nothing about joint</p> <p>8 infections.</p> <p>9 Q. What do you understand --</p> <p>10 MR. GORDON: It was clean contaminated</p> <p>11 surgery.</p> <p>12 Q. What do -- what do you think organ-space</p> <p>13 infections is?</p> <p>14 A. I would have assumed it was things like</p> <p>15 intrapleural infections or peritoneal infections. But</p> <p>16 your point is well taken. I can't define that term</p> <p>17 right now.</p> <p>18 Q. Okay. Now what was the change in skin</p> <p>19 preparation protocol during McGovern?</p> <p>20 A. The adoption of chlorhexidine as opposed to</p> <p>21 povidone-iodine, which was effected in October of</p> <p>22 2010.</p> <p>23 Q. You reference here that the "CDC found</p> <p>24 'high-quality evidence suggested a benefit of CHG-</p> <p>25 alcohol [chlorohex -- chlorhexidine gluconate-alcohol]</p>

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<p style="text-align: right;">Page 174</p> <p>1 as compared with aqueous iodophor." Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. Okay. There was no point in time during the</p> <p>4 McGovern period where aqueous iodophor was being used.</p> <p>5 A. I believe that's the povidone-iodine analog.</p> <p>6 Q. But it wasn't the same.</p> <p>7 A. It may not have been exactly the same.</p> <p>8 There were several variants of the iodine that was</p> <p>9 used.</p> <p>10 Q. Okay. And you think that a -- that even</p> <p>11 though there -- well let me strike that and ask it a</p> <p>12 different way.</p> <p>13 If it wasn't aqueous iodophor that was ever</p> <p>14 used for McGovern, what relevance if any does the CDC</p> <p>15 findings that you've stated here have?</p> <p>16 A. This statement that chlorhexidine, in the</p> <p>17 views of CDC, was preferable to what was then the most</p> <p>18 used iodine for skin treatment was meaningful to me.</p> <p>19 Q. So if something is slightly different, you</p> <p>20 still think it's okay to use it and extrapolate to</p> <p>21 that in connection with your conclusions in this case?</p> <p>22 A. I thought that there was high-quality</p> <p>23 evidence that this chlorhexidine was useful. But I</p> <p>24 understand your question about the direct comparison.</p> <p>25 Q. Then you also cite here -- or you state,</p>	<p style="text-align: right;">Page 176</p> <p>1 randomization.</p> <p>2 MS. CONLIN: You don't need to help him.</p> <p>3 I'm trying to get his understanding, Mr. Gordon, of</p> <p>4 what he had in mind when he --</p> <p>5 MR. GORDON: Jan, we can --</p> <p>6 If you -- if you want to know what was in</p> <p>7 one of the dozens of articles he cited, you can either</p> <p>8 take the time and he'll read through it all, or I --</p> <p>9 You know, sorry, I won't point him to it.</p> <p>10 But just so I understand, next time he'll -- he'll --</p> <p>11 he'll read it in its entirety.</p> <p>12 A. Okay. So it's the "Placebo soap and</p> <p>13 ointment were identical to the active treatment except</p> <p>14 for the active ingredients," so it was inactive.</p> <p>15 Q. So the placebo didn't have any antimicrobial</p> <p>16 effect; correct?</p> <p>17 A. That's my understanding.</p> <p>18 Q. Okay. So do you think it's appropriate to</p> <p>19 rely on a placebo study for your conclusion that the</p> <p>20 change in skin preparation during the McGovern study</p> <p>21 was a confounder?</p> <p>22 A. I think it reflects the fact that the two</p> <p>23 were interactive and complementary; that is, the</p> <p>24 mech -- the chlorhexidine and the screening. But I do</p> <p>25 understand that this is a comparison against placebo.</p>
<p style="text-align: right;">Page 175</p> <p>1 "There is also evidence that the combination of MSSA</p> <p>2 screening and chlorhexidine was complementary,</p> <p>3 resulting in a five-fold reduction in deep SSI</p> <p>4 compared -- compared to the placebo." Do you see</p> <p>5 that?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And let me pull that out for you.</p> <p>8 (Exhibit 20 was marked for</p> <p>9 identification.)</p> <p>10 BY MS. CONLIN:</p> <p>11 Q. I have handed you what's been marked as</p> <p>12 Borak Exhibit 20, which is the Bode reference which</p> <p>13 supports your statement in your report that there's</p> <p>14 also evidence that a combination of MSSA screening and</p> <p>15 chlorhexidine was complementary, resulting in a</p> <p>16 five-fold reduction in deep SSI compared to placebo;</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Now what was the placebo that was</p> <p>20 used in this study?</p> <p>21 A. I would have to look back.</p> <p>22 They describe it as "placebo," which I</p> <p>23 assume would -- may have been inactive, but I do not</p> <p>24 know. I don't see a description of --</p> <p>25 MR. GORDON: It's on page 11, the</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. Right. And so did you see anything that had</p> <p>2 a comparison that showed a statistical difference</p> <p>3 between the skin preparation used at the beginning of</p> <p>4 the McGovern study and the skin preparation that was</p> <p>5 implemented in October 2010?</p> <p>6 A. The iodophor is the only head-to-head that I</p> <p>7 can point to here at this moment.</p> <p>8 Q. Okay. And you know that wasn't the exact</p> <p>9 one; correct?</p> <p>10 A. I think it was not exact. I could look it</p> <p>11 up again. I know I looked at it at one time.</p> <p>12 Q. Do you have any evidence as you sit there --</p> <p>13 A. As I sit here today --</p> <p>14 Q. -- of a pub -- of a published study that</p> <p>15 suggests a material difference between the two skin-</p> <p>16 preparation protocols and a risk of a deep joint</p> <p>17 infection?</p> <p>18 A. I don't know that I can point to one now,</p> <p>19 but this again is something to which I will defer to</p> <p>20 Dr. Wenzel.</p> <p>21 Q. Okay. But without evidence, you're still</p> <p>22 comfortable opining that there is an association, at</p> <p>23 least as it relates to skin preparation; correct?</p> <p>24 A. I think I was carefully nuanced in my</p> <p>25 statement, which was "To the extent that use of</p>

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<p style="text-align: right;">Page 178</p> <p>1 chlorhexidine reduced infections, it would be a 2 confounder." 3 Q. But my point is is you -- you said at the 4 beginning of this module that we started that you do 5 believe it's a confounder, but you'll agree with me 6 that you don't have any evidence that the skin -- 7 change in skin preparation during the McGovern period 8 was -- 9 A. I do not have a direct comparison -- 10 Q. Right. 11 A. -- to offer you today. 12 Q. Right. But you're still comfortable saying 13 there's an association. 14 A. I think that there might be. 15 Q. Okay. There might be? 16 A. I don't have any evidence to ful -- complete 17 the last sentence, which I gave you before, which was 18 that if there was a reduction from the chlorhexidine, 19 it would be a confounder, and I don't have any field 20 data in the McGovern study showing that it wasn't. 21 Q. All right. I'd like to go to your next 22 section -- 23 Actually, let's go back to page 12. 24 MS. CONLIN: Actually, before we go there, 25 can you pull out Exhibit 9 from yesterday, Mr.</p>	<p style="text-align: right;">Page 180</p> <p>1 you to -- if that means your computer screwed up, I 2 don't want to -- 3 THE REPORTER: Let's go off the record, 4 please. 5 (Discussion off the record.) 6 BY MS. CONLIN: 7 Q. So I take it during the break you did some 8 internet searching in connection with your iodine -- 9 aqueous iodophor; is that right? 10 A. Correct. 11 Q. And that's something that you've learned 12 since you've been sitting here? 13 A. It's something I affirmed in my mind since I 14 was sitting here after your -- you took a break. 15 Q. Yeah. Go ahead. 16 A. Yeah. It's the same thing as povidone- 17 iodine. 18 Q. And in connection with your CDC statement 19 there, do you know whether the CDC was referencing 20 wound infections generally versus deep joint 21 infections? 22 A. I can't tell you that right now. 23 Q. Okay. So back to the point before the 24 break: As you sit here today, you don't know of any 25 published study that suggests a change -- the change</p>
<p style="text-align: right;">Page 179</p> <p>1 Stirewalt. 2 (Holford Exhibit 9 handed to the witness.) 3 THE WITNESS: Thank you. 4 Q. I've handed you what was marked as Holford 5 Deposition Exhibit 9, which is the Darouiche study 6 entitled "Association of Airborne Microorganisms in 7 the Operating Room With Implant Infections: A 8 Randomized Controlled Trial." Do you see that? 9 A. Yes, I do. 10 Q. And do you -- do you agree with me that an 11 RCT is, in terms of the pecking order of evidence that 12 you rely on in an epidemiologic study, a step above 13 observational studies? 14 A. Generally, if it's well done. 15 Q. Okay. And you see it says the objective is 16 "To evaluate the association" -- 17 By the way, do you know if this -- this is 18 the same Dr. Darouiche that you relied on in 19 connection with your opinions regarding skin 20 preparation; -- 21 A. I'm aware. 22 Q. -- correct? 23 MR. GORDON: Dick, your -- 24 It (referring to realtime screens) stopped. 25 I don't -- I don't care for myself, but I just want</p>	<p style="text-align: right;">Page 181</p> <p>1 in skin preparation during the McGovern period 2 creates -- or is a confounder associated with risk of 3 infection; correct? 4 A. I cannot tell you whether article 33 5 specifically looked at that, no, not now as we are 6 sitting here. 7 Q. Now if we can turn to Holford Deposition 8 Exhibit 9, the article entitled "Association of 9 Airborne Micronis -- Microorganisms in the Operating 10 Room With Implant Infections....," you see -- I think 11 we talked about this before the break -- that Dr. 12 Darouiche is the same doctor who you cited in 13 connection -- his study in connection with your skin- 14 preparation section of your report; correct? 15 A. That's correct. 16 Q. And the objective of this article is "To 17 evaluate the association of airborne colony-forming 18 units (CFU) at incision sites during implantation of 19 prostheses with incidence of either incisional or 20 prosthesis-related surgical site infections;" correct? 21 A. Yes. 22 Q. Okay. And if we can take a look at the last 23 page of this, the "In conclusion....," Drs. Darouiche 24 and the other study authors of this randomized 25 clinical trial write, quote, "In conclusion, our</p>

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<p style="text-align: right;">Page 182</p> <p>1 results indicate that CFU contamination of air at the 2 incision site is a risk factor for implant but not 3 incisional infections. CFU contamination is related 4 to the particulate density in the air at the incision 5 site, and both CFU and particulate density are a 6 function of the number of people in the operating 7 room. Limiting airborne CFU contamination at the 8 incision site can be expected to lower implant 9 infection risk." Do you see that? 10 A. I see that. 11 Q. And you didn't opine on this particular 12 article or challenge the validity of the RCT that is 13 described in Holford Deposition Exhibit 9; correct? 14 A. This paper? Yes, I did not. This paper 15 does not deal with Bair Hugger. 16 Q. Well it deals with CFUs in the air near the 17 implant; correct? 18 A. Yes. Yes. 19 Q. Okay. And you've already stated you don't 20 have an opinion whether Bair Hugger increases CFUs in 21 the air at the incisional site; correct? 22 MR. GORDON: Objection, mischaracterizes his 23 testimony. 24 A. I said I did not have such an expert 25 opinion.</p>	<p style="text-align: right;">Page 184</p> <p>1 Q. Okay. Can I refer to the Gentamicin period 2 as Gen and the Gentamicin plus Teicoplanin as GenTeic? 3 A. Sure. 4 Q. Okay. And you'll understand what I'm 5 referring to. 6 A. I think so. 7 Q. And I take it that you found the change in 8 prophylactic antibiotics to be a confounder; am I 9 right? 10 A. It appeared to confound, yes. 11 Q. Okay. Meaning that there is an association 12 between the change in the -- in -- from Gen to GenTeic 13 and risk of infection; correct? 14 A. Yes. And they were differentially -- the 15 antibiotics were differentially associated with the 16 two different warming units. 17 Q. What do you mean by "warming units?" 18 A. Bair Hugger versus Hot Dog. 19 Q. Oh, okay. 20 What investigation did you do to ascertain 21 that, with respect to prosthetic joint infections -- 22 not just infections in general but prosthetic joint 23 infections since that's what we're talking about -- 24 that a change from Gen to GenTeic would be a 25 confounder?</p>
<p style="text-align: right;">Page 183</p> <p>1 Q. Right. And you hadn't seen the fact that 2 the manufacturer of the Bair Hugger warned at the FDA 3 of the risk of airborne contamination; correct? 4 MR. GORDON: Object to the form of the 5 question. 6 A. I -- if you'll -- 7 I think you're referring to that five oh -- 8 512(k) or something? 9 Q. 510(k), yes. 10 A. I think there was a statement there that 11 there was no evidence of infections resulting 12 therefrom. 13 Q. I didn't ask you about that. Can you answer 14 my question? 15 A. Ask the question again. 16 Q. Sure. 17 MS. CONLIN: Could you read it back, Mr. 18 Court Reporter. 19 (Record read by the court reporter.) 20 A. I guess that was a statement in that paper. 21 Q. I'd like to turn back now to page 12 of your 22 report, the prophylactic antibiotics. And you 23 understand that during the McGovern period there was a 24 change in Gentamicin to Gentamicin plus Teicoplanin? 25 A. Yes.</p>	<p style="text-align: right;">Page 185</p> <p>1 A. Well I read a lot of literature and I 2 evaluated, as I could, the papers that were put in 3 front of me by my search on McGowan -- McGovern, and I 4 looked at statements from Dr. Reed and others that 5 seemed to be that there was evidence that there was an 6 increase in infections when Gentamicin was used alone 7 and a decrease when Teicoplanin was added. 8 Q. Well if anything, then, GenTeic would 9 increase the risk of deep joint infections in Hot Dog; 10 correct? 11 A. Why would that be? 12 Q. Well did you -- did you analyze whether 13 there was an increase or decrease in infections 14 related to the Gen versus GenTeic period, or did you 15 rely on Professor Holford for that analysis? 16 A. I -- I didn't independently review any 17 arithmetic calculations, if that's your question. 18 Q. Okay. Well you understand that during the 19 Hot Dog period GenTeic was used; correct? 20 A. Correct. 21 Q. Exclusively. All right. 22 Did you understand that, based on Professor 23 Holford's analysis, patients who received Gen had a 24 deep joint infection rate of 1.92 while patients who 25 received GenTeic had a 3.13 percent infection rate?</p>

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<p style="text-align: right;">Page 186</p> <p>1 A. Would you point me to where those numbers 2 are found?</p> <p>3 Q. I'm just asking if you know.</p> <p>4 A. I --</p> <p>5 Off the top of my head, I don't remember the 6 numbers.</p> <p>7 Q. Okay. So how can you determine that 8 something is a confounder if you didn't even look at 9 that issue as it relates to the infection rates 10 between the two?</p> <p>11 A. On the numerical thing, I relied upon Dr. 12 Holford's mathematical analysis.</p> <p>13 Q. Well, are you aware of any evidence showing 14 that antibiotics are of limited value in warding off 15 or preventing deep joint infections?</p> <p>16 MR. GORDON: Object to the form of the 17 question.</p> <p>18 A. I -- I have read, as you asked me earlier, 19 that biofilm can reduce the effectiveness of 20 antibiotics, if that was your question.</p> <p>21 Q. Right. And it -- it basically creates a 22 slime or a -- a -- a film over the infection and 23 antibiotics can't get at it; correct?</p> <p>24 MR. GORDON: Same objection.</p> <p>25 A. I -- I'm not sure if that's how I would</p>	<p style="text-align: right;">Page 188</p> <p>1 A. There was a series. One of them was the 2 differential capacity of the antibiotics to act upon 3 the bacteria that were most commonly associated with 4 the infections, a second I thought interesting was the 5 comment which I've quoted from Dr. Reed who said that 6 "Our infection rate doubled when we went to 7 Gentamicin," and I am sure that I -- there were others 8 at the moment I can't think of by name which have 9 shown the effectiveness of prophylactic antibiotics. 10 But in large part I would defer that, in terms of the 11 effectiveness, to Dr. Wenzel.</p> <p>12 Q. Well if you don't have an opinion on the 13 effectiveness, how can you opine that it's a 14 confounder?</p> <p>15 A. I have a statement from Dr. Reed from this 16 operating room who said that the infection rate went 17 up significantly when they used Gentamicin, and we 18 have evidence that the infectious rate -- infection 19 rate declined after the adoption of Teicoplanin.</p> <p>20 Q. I thought you just said you didn't do that 21 analysis.</p> <p>22 A. I -- I was looking at just the -- the -- the 23 crude numbers. I didn't do the analysis, I looked at 24 Dr. Holford's.</p> <p>25 Q. So you're relying on Dr. Reed for this</p>
<p style="text-align: right;">Page 187</p> <p>1 describe it, but yes, I think in effect that's what 2 happens.</p> <p>3 Q. And you can't deliver that much antibiotic 4 to a patient that can penetrate that, and that's one 5 of the reasons why deep joint infections take a while 6 to show up; correct?</p> <p>7 MR. GORDON: Same objection.</p> <p>8 A. I don't think -- I don't think that's why it 9 takes a while for them to show up, but --</p> <p>10 Q. Have you seen articles that have concluded 11 that the benefits of prophylactic antibiotics in 12 reducing infection rates after clean surgeries are 13 unclear?</p> <p>14 MR. GORDON: Object to the form of the 15 question.</p> <p>16 A. I don't know that I've seen that.</p> <p>17 Q. Okay. That wasn't something you came 18 across?</p> <p>19 A. I don't remember it.</p> <p>20 Q. Well how did you go about making the 21 decision that the change in prophylactic antibiotics 22 would have a material effect on risk of infection in a 23 prosthetic joint?</p> <p>24 MR. GORDON: Object to the form of the 25 question.</p>	<p style="text-align: right;">Page 189</p> <p>1 statement that the infection rate doubled when we went 2 to Gentamicin; correct?</p> <p>3 A. That was his statement, yes.</p> <p>4 Q. Okay. And -- and that was a statement that, 5 when you read that, you said, "Okay, I'm going to rely 6 on Dr. Reed for that." Right?</p> <p>7 A. I thought that was an interesting statement.</p> <p>8 Q. And you said, "I'm going to rely on that;" 9 right?</p> <p>10 A. Yes.</p> <p>11 Q. And then when Dr. Reed said things you 12 didn't agree with, you just set those aside; isn't 13 that right?</p> <p>14 A. To some extent that's correct.</p> <p>15 Q. Okay. Cherry-picking, isn't that what it's 16 called?</p> <p>17 A. No, no, no, no. I can explain how I got 18 there, so that's not cherry-picking.</p> <p>19 Q. Okay. Do you know whether Dr. Reed was 20 talking about deep joint infections versus superficial 21 wound infections?</p> <p>22 A. Not without looking back at the document.</p> <p>23 Q. Okay. Do you know whether antibiotics are 24 better and perhaps more efficacious when it relates to 25 wound infections as opposed to deep joint infections?</p>

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<p style="text-align: right;">Page 190</p> <p>1 A. I -- I don't know for sure.</p> <p>2 Q. That wasn't something you investigated when</p> <p>3 you reached your conclusion that the change in</p> <p>4 antibiotics was a confounder as it related to deep</p> <p>5 joint infections during the McGovern period; correct?</p> <p>6 A. I did not independently investigate that</p> <p>7 question.</p> <p>8 Q. Do you believe that the -- that any changes</p> <p>9 in wound dressing post surgery during the McGovern</p> <p>10 period is a confounder?</p> <p>11 A. I believe they changed dressings after the</p> <p>12 end of the McGovern study.</p> <p>13 Q. Okay.</p> <p>14 (Exhibit 21 was marked for</p> <p>15 identification.)</p> <p>16 BY MS. CONLIN:</p> <p>17 Q. I've handed you what's been marked as</p> <p>18 Deposition Exhibit 21, which is an article by Dr.</p> <p>19 Melling et al, quote, "Effects of preoperative warming</p> <p>20 on the incidence of wound infection after clean</p> <p>21 surgery: a randomized controlled trial." Do you see</p> <p>22 that?</p> <p>23 A. I do.</p> <p>24 Q. And Dr. Melling was one of the individuals</p> <p>25 that you relied -- or the author of one of the other</p>	<p style="text-align: right;">Page 192</p> <p>1 A. I see that.</p> <p>2 Q. Okay. So this --</p> <p>3 I take it you had read this before you</p> <p>4 rendered your opinions in this case; correct?</p> <p>5 A. I'm sure I'd read this before I rendered my</p> <p>6 opinions.</p> <p>7 Q. Okay. And one of the reasons you decided</p> <p>8 that there wasn't evidence of an association between</p> <p>9 the Bair Hugger and the increased risk of infection is</p> <p>10 because there were studies on both sides; right? We</p> <p>11 talked about that this morning.</p> <p>12 A. I think that's right.</p> <p>13 Q. Okay. And this is an article that's saying</p> <p>14 that there's sort of studies on both sides on whether</p> <p>15 even administering any antibiotic -- or prophylactic</p> <p>16 antibiotic after a clean surgery is unclear; correct?</p> <p>17 A. That was the starting premise, yes.</p> <p>18 Q. Okay. But you've decided that the change in</p> <p>19 antibiotics was a confounder in connection with</p> <p>20 McGovern; correct?</p> <p>21 A. Based on the McGovern data, yes.</p> <p>22 Q. You know the authors said that it wasn't a</p> <p>23 confounder in their mind; correct?</p> <p>24 A. I think they did in their depositions.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 191</p> <p>1 references that you relied upon in connection with</p> <p>2 your opinions; correct? For example, reference number</p> <p>3 four on your list of documents relied upon.</p> <p>4 A. Yes. I skipped it somehow. Thanks.</p> <p>5 Q. All right. So this is --</p> <p>6 This author of Exhibit 21 is the same doctor</p> <p>7 as one of the other references that you relied upon in</p> <p>8 connection with your expert opinions in this case;</p> <p>9 correct?</p> <p>10 A. Presumably. And this may even be the same</p> <p>11 paper.</p> <p>12 Q. Okay.</p> <p>13 A. How do you like that?</p> <p>14 Q. All right. So if we can take a look under</p> <p>15 "Introduction," one, two, three -- four paragraphs</p> <p>16 down, it says, "Many factors have been shown to reduce</p> <p>17 the incidence of surgical wound infection, most of</p> <p>18 which are now part of best practice. The value of</p> <p>19 prophylactic antibiotics in clean-contaminated and</p> <p>20 contaminated surgery is not contentious but the</p> <p>21 benefits of prophylactic antibiotics in reducing wound</p> <p>22 infection rates after clean surgery remain unclear.</p> <p>23 Although it has been suggested that antibiotics are</p> <p>24 beneficial this idea has not been supported by other</p> <p>25 studies." Do you see that?</p>	<p style="text-align: right;">Page 193</p> <p>1 (Exhibit 22 was marked for</p> <p>2 identification.)</p> <p>3 BY MS. CONLIN:</p> <p>4 Q. I've handed you, sir, what's been marked as</p> <p>5 Deposition Exhibit 22, which is a study entitled</p> <p>6 "Prophylactic antibiotics in elective hip and knee</p> <p>7 arthroplasty," authored by Dr. Hickson among others.</p> <p>8 Do you see that?</p> <p>9 A. I do.</p> <p>10 Q. You see that Dr. Reed is also an author on</p> <p>11 this?</p> <p>12 A. I do.</p> <p>13 Q. Okay. If we can take a look at page 186 of</p> <p>14 this.</p> <p>15 A. May I just look at the abstract first,</p> <p>16 make --</p> <p>17 Q. Sure.</p> <p>18 A. Okay. Thank you.</p> <p>19 Q. Can you direct your attention to page 186 of</p> <p>20 this, and direct your attention to the second</p> <p>21 paragraph down starting with "Although..." It says,</p> <p>22 "Although there is a large body of evidence for the</p> <p>23 use of prophylactic antibiotics in primary hip and</p> <p>24 knee arthroplasty, there is no clear benefit to using</p> <p>25 one particular agent/regimen." Do you see that?</p>

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<p style="text-align: right;">Page 194</p> <p>1 A. I do.</p> <p>2 Q. Okay. Do you have any reason to dispute the</p> <p>3 statements by Drs. Reed and Hickson as reported in</p> <p>4 this --</p> <p>5 A. I --</p> <p>6 Q. -- article?</p> <p>7 A. I don't.</p> <p>8 Q. Okay. So I'd like to direct your attention</p> <p>9 to page 13 of your report regarding the MSSA</p> <p>10 screening.</p> <p>11 A. Yes.</p> <p>12 Q. And I take it you also find that there is an</p> <p>13 association between MSSA screening and an increased</p> <p>14 risk of a prosthetic joint infection; correct?</p> <p>15 A. I believe that's correct, yes.</p> <p>16 Q. Okay. And you said that there was screening</p> <p>17 implemented for MSSA, or methicillin sensitive</p> <p>18 Streptococcus aureus, correct, in January of 2010?</p> <p>19 A. Yes, I did say that.</p> <p>20 Q. Okay. And is it -- and you also say that</p> <p>21 there --</p> <p>22 Well, do you know if there was</p> <p>23 decolonization after that?</p> <p>24 A. That's my understanding.</p> <p>25 Q. And what was the decolonization protocol?</p>	<p style="text-align: right;">Page 196</p> <p>1 decolonization procedure is outlined. I'll just</p> <p>2 represent to you I -- I couldn't find it, so --</p> <p>3 MR. GORDON: I'll save you both time. It's</p> <p>4 not in there.</p> <p>5 A. I -- I --</p> <p>6 At the moment I don't see it. I'm not sure</p> <p>7 if it's in the table, which I can't see.</p> <p>8 Q. I'll represent to you that I blew that up</p> <p>9 and it doesn't say it there either, so I'm just</p> <p>10 curious --</p> <p>11 MR. GORDON: I'll -- I'll stipulate to that.</p> <p>12 MS. CONLIN: Okay.</p> <p>13 Q. So where -- where did you get this notion</p> <p>14 that the screening was followed by a decolonization</p> <p>15 with a topical antibiotic mupir --</p> <p>16 A. Mupirocin.</p> <p>17 Q. -- mupirocin?</p> <p>18 A. I think that I --</p> <p>19 If I didn't find it in here and if I did not</p> <p>20 see it in Dr. Reed's testimony, then I presume I</p> <p>21 assumed that it would be the only purpose for doing</p> <p>22 the MSSA screening; that is, to detect and then to</p> <p>23 respond to it.</p> <p>24 Q. Well I guess my point is is how do you know</p> <p>25 it was that particular topical antibiotic versus</p>
<p style="text-align: right;">Page 195</p> <p>1 A. I would have to look it up. And I think it</p> <p>2 was muc -- mupirocin that was used, but I could look</p> <p>3 at --</p> <p>4 Probably it was in Gillson, but I'm not</p> <p>5 sure.</p> <p>6 Q. Okay. In connection with --</p> <p>7 MS. CONLIN: Well I'll dig that out. Why</p> <p>8 don't we just take a quick break here; we've been</p> <p>9 going about an hour anyway.</p> <p>10 THE REPORTER: Off the record, please.</p> <p>11 (Recess taken.)</p> <p>12 (Exhibit 23 was marked for</p> <p>13 identification.)</p> <p>14 BY MS. CONLIN:</p> <p>15 Q. I've handed you, sir, what's been marked as</p> <p>16 Deposition -- Borak Deposition Exhibit 23, which is</p> <p>17 entitled "Implementing effective SSI surveillance" by</p> <p>18 Julie Gillson and Gail Lowdon.</p> <p>19 Is this what you were referencing before the</p> <p>20 break in connection with your understanding that once</p> <p>21 MSSA screening was undertaken in January of 2010,</p> <p>22 there was decolonization with a topical antibiotic?</p> <p>23 A. This is the article I was referring to.</p> <p>24 Q. Okay. And then I'd just ask you to point</p> <p>25 out for me where in the article the actual</p>	<p style="text-align: right;">Page 197</p> <p>1 something else?</p> <p>2 A. That is the one that has been used almost</p> <p>3 universally, so I -- I am reasonably certain that I --</p> <p>4 I would have expected that. And I thought I knew</p> <p>5 that, but at the moment sitting here I can't point to</p> <p>6 a place where I found that specific detail.</p> <p>7 Q. And you again, in connection with this MSSA</p> <p>8 screening, rely on statements by Dr. Reed; correct?</p> <p>9 A. Well I pointed to Dr. Reed's statement.</p> <p>10 Q. Well you relied on it; correct?</p> <p>11 A. Yes.</p> <p>12 Q. Okay.</p> <p>13 A. Oh, okay. There. Okay. So it is Dr. Reed</p> <p>14 who literally there said, "After MSSA screening, a</p> <p>15 decolonization was introduced," and I took for granted</p> <p>16 that that was referring to this time in this study of</p> <p>17 concern that we have with McGovern.</p> <p>18 Q. Okay. Did you do any analysis as to whether</p> <p>19 MSSA infections went up after MSSA screening and</p> <p>20 decolonization was implemented in January 2010?</p> <p>21 A. I understand from conversations -- I did not</p> <p>22 look at the raw data -- that there were none reported</p> <p>23 after the introduction of that process.</p> <p>24 Q. So you would disagree that there was an</p> <p>25 uptick in infections after MSSA screening was</p>

50 (Pages 194 to 197)

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<p style="text-align: right;">Page 198</p> <p>1 implemented?</p> <p>2 A. I thought that there were no MSSA</p> <p>3 infections.</p> <p>4 (Exhibit 24 was marked for</p> <p>5 identification.)</p> <p>6 BY MS. CONLIN:</p> <p>7 Q. I've handed you, sir, what's been marked as</p> <p>8 Borak Deposition Exhibit 24, which is a document</p> <p>9 entitled "Surveillance of surgical site infections in</p> <p>10 NHS hospitals in England." Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. Okay. And is this something you've seen</p> <p>13 before?</p> <p>14 A. I have seen documents that look like this.</p> <p>15 I don't know if this is the one I saw.</p> <p>16 Q. Okay. If we can direct your attention to</p> <p>17 page 30, --</p> <p>18 A. Yes.</p> <p>19 Q. -- Figure 11, "Trends in micro-organisms</p> <p>20 reported as causing inpatient SSIs, proportions with</p> <p>21 lower and upper 95 percent confidence, all surgical</p> <p>22 categories, NHS hospitals, England." Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. Okay. Now you'll see the dotted green line</p> <p>25 is MSSA infections; correct?</p>	<p style="text-align: right;">Page 200</p> <p>1 A. I would not have looked at this since this</p> <p>2 is a composite of all of the hospitals in England -- I</p> <p>3 think it is all of them -- and it is all forms of</p> <p>4 surgery, and so I'm not quite sure what one could have</p> <p>5 drawn from this or what it would have told me other</p> <p>6 than the fact that there was heterogeneity in the</p> <p>7 operating room procedures in the NHS hospitals.</p> <p>8 Q. Do you know which hospitals were included in</p> <p>9 this?</p> <p>10 A. I'm happy to look at the beginning.</p> <p>11 Q. Well you just said it includes all the</p> <p>12 hospitals. I'm wondering if you know that or you're</p> <p>13 just assuming that.</p> <p>14 A. I am assuming it based upon what I saw in a</p> <p>15 quick look at the document, but I'm happy to look</p> <p>16 further. "Since July 2008 hospitals were required" --</p> <p>17 I mean I'm happy to take time to look for</p> <p>18 the number, but --</p> <p>19 Q. No. I -- I was just curious, when you said</p> <p>20 that it included more hospitals than the three at</p> <p>21 issue in McGovern, whether you knew that or you were</p> <p>22 just speculating.</p> <p>23 A. Oh, no, no, no, I'm not speculating, but I</p> <p>24 don't know what the number is.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 199</p> <p>1 MR. GORDON: Dotted green or blue?</p> <p>2 MS. CONLIN: Well whatever. It's the one</p> <p>3 dotted line with the circle.</p> <p>4 Q. Do you see that?</p> <p>5 A. Yes.</p> <p>6 MS. CONLIN: Okay. And yeah, it does look</p> <p>7 blue, Mr. Gordon. Thank you. We'll refer to it as</p> <p>8 the dotted blue line.</p> <p>9 Q. You'll see that there's a reference point</p> <p>10 there of September 2008.</p> <p>11 Right here.</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And then if you look, based on this</p> <p>14 graph, MSSA infections went down between September</p> <p>15 2008 and October 2009; correct?</p> <p>16 A. It seems to be.</p> <p>17 Q. Okay. And then after October 2009 to</p> <p>18 November 2011, you'll see there's an uptick; correct?</p> <p>19 A. I do see that.</p> <p>20 Q. Okay. Is that something that you</p> <p>21 investigated in connection with your view that the</p> <p>22 MSSA screening renders the McGov -- is a confounder to</p> <p>23 the McGovern report?</p> <p>24 MR. GORDON: Object to the form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 201</p> <p>1 A. This is a composite of the NHS system. We</p> <p>2 are looking at, in McGovern, one hospital.</p> <p>3 Q. Okay. But you --</p> <p>4 Your view is that because the MSSA data on</p> <p>5 that chart we just looked at isn't specific to deep</p> <p>6 joint infections, it wouldn't be a fair comparison; is</p> <p>7 that right?</p> <p>8 A. No. It wouldn't be a fair comparison</p> <p>9 because it's looking at, I believe, most if not all of</p> <p>10 the NHS hospitals in England. I don't know about</p> <p>11 their implementation of procedures and protocols. I</p> <p>12 believe I saw something here about a lack of</p> <p>13 consistency in the applications of protocols. I think</p> <p>14 there are a variety of other considerations. So I</p> <p>15 wouldn't use this to inform my thinking about</p> <p>16 Northumbria.</p> <p>17 Q. And one of the reasons that you just stated</p> <p>18 that you didn't think it would be a fair comparison is</p> <p>19 because it's including other surgeries, not just deep</p> <p>20 joint infections; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Other types of infections.</p> <p>23 A. Yes.</p> <p>24 Q. And you don't think it would be fair to</p> <p>25 extrapolate from one type of infection in one part of</p>

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<p style="text-align: right;">Page 202</p> <p>1 the body to a deep joint infection even if it's MSSA; 2 correct? 3 A. I -- I -- I -- 4 Yes. I think this would raise the question 5 whether this added or altered my thinking, and I 6 referred ultimately to a comment which came literally 7 from Dr. Reed who said that "In the fight against 8 PJI" -- prosthetic joint infections -- "after MSSA 9 screening and decolonization was introduced, one NHS 10 joint replacement unit, the MSSA infection was reduced 11 from .84 to .26." I believe that is speaking about 12 Wansbeck, though in looking at the document I couldn't 13 tell which of the three hospitals it was, but I 14 presume it is because it's where there was the data. 15 MS. CONLIN: Move to strike as non- 16 responsive. 17 Can you read my question back? 18 (Record read by the court reporter.) 19 A. I -- I have difficulty extrapolating from 20 this document. I might also have -- 21 Q. I didn't ask you that. I asked you a 22 straight-up question. 23 MS. CONLIN: Could you read it back again. 24 (Record read by the court reporter.) 25 A. It might not be fair.</p>	<p style="text-align: right;">Page 204</p> <p>1 says, "The majority of studies detected S. aureus 2 colonization using cultures, most SSIs were defined by 3 CDC criteria, the majority of studies did not 4 differentiate between superfer -- superficial versus 5 deep infections, and most of the patients who 6 underwent decolonization were positive for S. aureus 7 on nasal screens." Do you see that? 8 A. I do. 9 Q. In connection with your discussion of MSSA 10 screening, you bundled infections regardless of 11 whether they were deep joint infections; correct? 12 MR. GORDON: Object to the form of the 13 question. 14 A. I cited a paper which I think may have 15 bundled it. 16 Q. In -- in support of your belief that the 17 implementation of MSSA screening and decolonization is 18 a confounding factor in McGovern; correct? 19 A. Yes. Correct. 20 (Exhibit 26 was marked for 21 identification.) 22 THE WITNESS: Thank you. 23 BY MS. CONLIN: 24 Q. I've handed you what's been marked as Borak 25 Exhibit 26, which is a JAMA survey entitled "Centers</p>
<p style="text-align: right;">Page 203</p> <p>1 (Exhibit 25 was marked for 2 identification.) 3 BY MS. CONLIN: 4 Q. I've handed you, sir, what's been marked as 5 Borak Exhibit 25, which I think is your reference -- 6 A. I think it's number 30. 7 Q. -- your reference number 30; correct? 8 A. I believe that's correct. 9 Q. Thank you. Okay. And this was one of the 10 things that you relied on to suggest that 11 decolonization with a topical antibiotic, mupirocin, 12 has been shown to significantly reduce risk of post- 13 surgical infections, including hip and knee 14 replacements; correct? 15 A. Yes. 16 Q. Okay. I'd like to direct your attention to 17 the third paragraph of this article. 18 A. After the introduction or in the abstract? 19 Q. Internal page 2385. Got a chart at the top. 20 A. Third page. I thought you said paragraph. 21 Okay. 22 Q. In the paragraph about "Of the 19 23 studies..." 24 A. "Of the 19 studies..." Yes. 25 Q. On the right-hand side, midway down, it</p>	<p style="text-align: right;">Page 205</p> <p>1 for Disease Control and Preven -- Prevention Guideline 2 for the Prevention of Surgical Site Infection, 2017;" 3 correct? 4 A. Correct. 5 Q. And this was something that you relied on in 6 connection with your opinions in this case; correct? 7 A. Correct. 8 Q. Okay. I'd like to direct -- 9 Now by the way, you understand that this 10 particular recommendation didn't advocate one type of 11 patient warming over another; correct? 12 A. I don't remember that. 13 Q. Okay. That they said keep patients warm, 14 but they didn't advocate a specific -- 15 A. Okay. That is probably correct. I don't 16 specifically remember. 17 Q. And you're not suggesting that there's 18 something special about the Bair Hugger that keeps a 19 patient warmer; correct? 20 A. I understood that the Bair Hugger warmed 21 more quickly, but I can't tell you where I know that 22 from. 23 Q. Okay. Now if we can take a look at E4, 24 under "Normothermia," do you see that -- 25 A. Yes.</p>

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<p style="text-align: right;">Page 206</p> <p>1 Q. -- in the left-hand side underneath 2 "Glycemic Control?" 3 A. Yes. 4 Q. At the end of it it says, "...Other 5 Guidelines section of the narrative summary for this 6 question (eAppendix 1 one of the Supplement)." Do you 7 see that? 8 A. Yes. 9 Q. Okay. Did you look at that supplement to -- 10 A. I believe I did. 11 Q. Okay. So you're aware that in that 12 supplement the CDC found no benefit to using CHG- 13 alcohol compared to iodophor alcohol; correct? 14 A. I actually don't recall that. 15 Q. Okay. Are you aware that the CDC found no 16 benefit to CHG versus povidone-iodine? 17 A. I don't recall that. 18 Q. Okay. Would that be something that would be 19 important in connection with your view that the change 20 in skin preparation is a confounder that undercuts the 21 validity of McGovern? 22 A. I would probably go back and look at it 23 again, and I may do so tonight. 24 Q. Okay. Are you aware that that appendix 25 found no benefit to using enoxaparin, which is a --</p>	<p style="text-align: right;">Page 208</p> <p>1 blind path. 2 Q. Okay. And you set aside the 3 thromboprophylaxis discussion because you didn't see a 4 comparison between -- between trinzaparin and Xarelto 5 directly; correct? 6 A. I did not see such a comparison. 7 Q. And you felt like it would be inappropriate 8 to use the reference to enoxaparin even though it's 9 similar to trinzaparin because it's different; is that 10 right? 11 A. It's different. 12 Q. And that's one of the reasons you set it 13 aside; correct? 14 A. Correct. 15 Q. Now I'd like to direct your attention to 16 page nine of your expert report, Borak Exhibit 1, "The 17 McGovern Study: Background." Are you there? 18 A. I am. 19 Q. Okay. And in paragraph 22 you say, "The 20 report -- report by McGovern is the only published 21 study that purports to show an increased risk of SSI 22 associated with the use of the Bair Hugger." 23 A. I did say that. 24 Q. Okay. And there -- 25 Since that time there's been the Augustine</p>
<p style="text-align: right;">Page 207</p> <p>1 basically a low-molecular-weight heparin similar to 2 trinzaparin, compared to Xarelto, which -- 3 A. I know that it -- 4 MR. GORDON: Object to the form of the 5 question. 6 A. They -- they reviewed a number of studies, 7 none of which compared trinzaparin. 8 Q. So you were aware of that. 9 A. Yes. 10 Q. And your point is is you can't rely on that 11 because enoxaparin is -- even though it's another type 12 of low-molecular-weight heparin, it's not the same as 13 trinzaparin; correct? 14 A. Well that was one, and the second is that 15 the papers they reference don't actually define 16 surgical infection. 17 Q. So with respect -- 18 Well fair point. You'd agree with me that 19 you got to know whether it's a deep joint infection or 20 some other type of infection. 21 A. I -- I -- I didn't -- I didn't know what 22 they were looking at. I tried. It was cited only -- 23 In each of the four papers they reference 24 there, it is only cited in a table with a footnote, 25 and the footnote doesn't lead -- is a -- is a -- is a</p>	<p style="text-align: right;">Page 209</p> <p>1 paper that's been published; correct? 2 A. Correct. 3 Q. And I take it that doesn't change your 4 views. 5 A. No. I think little of the Augustine paper. 6 Q. You think little of the Aug -- 7 Why is that? 8 A. It doesn't seem to follow its protocol. It 9 seems to have cherry-picked data. 10 Q. What kind of cherry-picking? 11 A. Hmm. There are data from Ridgeview Medical 12 Center, that were apparently provided under whatever 13 process legally, which shows a compilation of knee and 14 hip surgeries and infectious rates for four years, 15 2006, 2007, 2008, 2009. Looking at the recent 16 Augustine paper, it appears that he only dealt with 17 the knees, not the hips nor the two combined, that he 18 compared 2006 knees to 2008 and 2009 knees, which was 19 not at all what he said would be the protocol, which 20 was a two-month or three-month washout period, and 21 that he selectickly -- selectively excluded the 2007 22 data. And so it doesn't look to me as though the 23 Augustine paper is based upon legitimate data, it 24 looks as though -- well "legitimate" -- real but 25 selected in a way to influence the appearance of an</p>

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<p style="text-align: right;">Page 210</p> <p>1 outcome.</p> <p>2 Q. How about the other two centers?</p> <p>3 A. I don't have any data on them.</p> <p>4 Q. Now in paragraph 24 --</p> <p>5 Oh, by the way, is there anything else that</p> <p>6 you want to say about why you think very little of the</p> <p>7 Augustine paper?</p> <p>8 A. Well it's clear that he doesn't provide</p> <p>9 enough information about the cases, and his statement,</p> <p>10 which is that nothing else changed, is contradicted by</p> <p>11 statements from that Ridgeview Medical Center itself,</p> <p>12 so my sense of it is that the data are not what he</p> <p>13 presents or that he misrepresents the data, and that</p> <p>14 he excluded a year's worth of data which would not</p> <p>15 have enhanced the comparison, that he deviated from</p> <p>16 the protocol, and that he excluded the hip data.</p> <p>17 Q. Excluded the what? I'm sorry.</p> <p>18 A. Excluded the hip data --</p> <p>19 Q. Oh "hip." Okay. Yeah.</p> <p>20 A. -- and did not present the paper properly.</p> <p>21 He says that he did a replica or something -- I'm</p> <p>22 paraphrasing -- of the McGovern study, but of course</p> <p>23 he clearly did not.</p> <p>24 Q. If the --</p> <p>25 Is that everything? I'm just trying to make</p>	<p style="text-align: right;">Page 212</p> <p>1 there was one more infection in each group, then</p> <p>2 running those numbers is a 2.76 increased risk of</p> <p>3 infection. Would you consider that substantial?</p> <p>4 MR. GORDON: It's actually 2.86.</p> <p>5 MS. CONLIN: 2.86. Thank you for that</p> <p>6 correction.</p> <p>7 A. The word "substantial" is awfully</p> <p>8 subjective. I don't -- I don't think I used it, but</p> <p>9 maybe I would. I would not use it necessarily for</p> <p>10 2.76.</p> <p>11 Q. But for 3.8, you would call that a</p> <p>12 significantly increased odds ratio.</p> <p>13 A. I -- I think it was significantly increased.</p> <p>14 I think that's what the arithmetics showed.</p> <p>15 Q. Well you used the term "significantly</p> <p>16 increased odds ratio" --</p> <p>17 A. Yes.</p> <p>18 Q. -- for SSI during the Bair Hugger period --</p> <p>19 A. Yes.</p> <p>20 Q. -- if the McGovern data is accurate;</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Now in paragraph 24 you say, "The</p> <p>24 McGovern authors noted that 'unfortunately' during the</p> <p>25 study period there was a change in the prophylactic</p>
<p style="text-align: right;">Page 211</p> <p>1 sure.</p> <p>2 A. For the moment. It's possible something</p> <p>3 else will occur to me, but I haven't pulled out my</p> <p>4 notes.</p> <p>5 Q. Okay. If the McGovern study is valid, would</p> <p>6 you agree with me that there is a substantial increase</p> <p>7 in the risk of infection through use of the Bair</p> <p>8 Hugger?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question.</p> <p>11 A. Hypothetically, if there were no problems</p> <p>12 with the McGovern paper, then its conclusions could be</p> <p>13 relied upon.</p> <p>14 Q. Okay. And it would show a substantial</p> <p>15 increased risk of a deep joint infection --</p> <p>16 A. Hypothetically, if it were different --</p> <p>17 Q. -- through use of Bair Hugger.</p> <p>18 A. Hypothetically, if there were no problems</p> <p>19 with the McGovern paper and if the results as</p> <p>20 presented were correct, then it would show a 3.8-fold</p> <p>21 increased risk with the Bair Hugger that was</p> <p>22 statistically significant.</p> <p>23 Q. Okay. And if --</p> <p>24 One of the things that Professor Holford did</p> <p>25 is say, well, there -- Dr. Reed testified he thought</p>	<p style="text-align: right;">Page 213</p> <p>1 antibiotic regimen and two changes in their</p> <p>2 thromboprophylaxis regimen." Do you see that?</p> <p>3 A. I do.</p> <p>4 Q. Where does that quote "unfortunately" come</p> <p>5 from?</p> <p>6 A. I'd have to look and see whether it's in</p> <p>7 McGovern or in some of the depositions.</p> <p>8 Q. Okay. So you weren't suggesting an</p> <p>9 attribution to the article itself.</p> <p>10 A. I don't know. I can look and see. I don't</p> <p>11 remember.</p> <p>12 Q. Okay. And you write in 25 that "The authors</p> <p>13 concluded that their study did not establish a causal</p> <p>14 basis for an association between Bair Hugger and risk</p> <p>15 of SSI...;" correct?</p> <p>16 A. Yes, that's correct.</p> <p>17 Q. Okay. Now you read the depositions of at</p> <p>18 least some of the authors; correct?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And you understand that they hadn't</p> <p>21 done a full epidemiological study at the time the</p> <p>22 McGovern paper was published; correct?</p> <p>23 A. I'm not sure what you mean by "a full</p> <p>24 epidemiological study," but perhaps you can refer to</p> <p>25 the statement that you're referring to.</p>

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<p style="text-align: right;">Page 214</p> <p>1 Q. Well you understand that they hadn't gone 2 out and done a bunch of research beyond what -- the 3 McGovern paper itself. I mean they -- they -- they 4 were reporting on work they did; correct? 5 A. They were reporting the data that they said 6 they had collected at this hospital. 7 Q. Okay. And, for example, they don't 8 reference the Stocks paper or the Darouiche paper; 9 correct? 10 A. They did not refer to that, but I -- 11 Yes, I don't think they did. 12 Q. Okay. And you're aware that at least one of 13 the authors testified under oath, under penalty of 14 perjury, that a causal connection if properly 15 qualified could be made; correct? 16 MR. GORDON: Object to the form of the 17 question, mischaracterizes the testimony. 18 A. I -- I don't recall that. Which expert was 19 that -- or which author? 20 Q. I think it was Dr. Reed. I can dig it out. 21 Do you recall reading that? 22 A. I don't specifically. I've cited something 23 else from Dr. Reed's deposition. 24 Q. Because you did cite throughout your report 25 where helpful your position statements that were made,</p>	<p style="text-align: right;">Page 216</p> <p>1 to imply a causal connection? 2 "Answer: If properly qualified, yes." 3 Do you see that? 4 A. I'm sorry, direct me to which page. 5 Q. Page one -- internal page 115. Bottom of 6 114, top of 115. Do you see that? 7 A. I'm looking at the next interaction, which 8 is "What would the proper qualifications be?" 9 I see what you've read. 10 Q. Okay. And it's your opinion that not only 11 can you not draw a causal connection based on a review 12 of all the evidence, but you can't even suggest an 13 association between the Bair Hugger and an increased 14 risk of infection; isn't that right? 15 A. No. There's clearly an association that's 16 been made by the McGovern paper. What I've said is I 17 find no evidence to indicate that there is a 18 causation. 19 Q. Well let's take a look. I thought we went 20 over this this morning. It took us a while to 21 establish it. 22 You write in paragraph 74c, "The McGovern 23 report relied on truncated and incorrect -- 24 incorrectly tabulated data. When those irregularities 25 are corrected, the study data do not pry -- provide</p>
<p style="text-align: right;">Page 215</p> <p>1 correct, by both Drs. Reed and McGovern? 2 A. I certainly quoted from them, yes. 3 (Discussion off the stenographic record.) 4 (Exhibit 27 was marked for 5 identification.) 6 BY MS. CONLIN: 7 Q. I've handed you a portion of Dr. McGovern's 8 deposition. 9 By the way, did you get both days of Dr. 10 McGovern's deposition? 11 A. Yes, I did. 12 Q. Okay. 13 A. But forgive me, I thought you were asking me 14 a question a moment ago about Dr. Reed. 15 Q. No, I asked you about one of the authors. 16 A. Oh. And I thought you said it was Dr. Reed. 17 Maybe I'm wrong. Maybe I misheard. 18 Q. And if you take a look at the bottom of page 19 114 where Mr. Gordon was questioning him: 20 "Question: Based on the evidence, you 21 believe it would have been reasonable to imply there 22 was a causation?" 23 Mr. Gordon, quote -- or -- 24 "Question: Based on the evidence, you 25 believe it would have been reasonable for your paper</p>	<p style="text-align: right;">Page 217</p> <p>1 evidence that the Bair Hugger is associated with a 2 significant increase in SSI;" correct? 3 A. The operative word there is "a significant 4 increase," and once those data errors are corrected, 5 the association becomes non-significant. 6 Q. Well you know that the study authors, in 7 addition to saying they checked the numbers three 8 times before they went in the final report, Dr. Reed, 9 for example, said that if you added one infection on 10 each side, it would change the odds ratio very -- very 11 slightly; right? 12 A. I -- I saw such a statement. 13 Q. Okay. And you -- you disagree with that, 14 too; don't you? 15 A. I relied upon Dr. Holford's calculations 16 based on that, -- 17 Q. Okay. 18 A. -- both in his paper and in -- in his report 19 and in footnote one of his report. 20 Q. But you would disagree with Dr. Reed that it 21 would change the odds ratio very slightly; correct? 22 A. I don't know what he meant by "very 23 slightly." But yes, I don't agree that it would have 24 retained significance. 25 Q. Even if it had at p-value of under .05?</p>

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<p style="text-align: right;">Page 218</p> <p>1 A. I would have to see that.</p> <p>2 Q. Okay. Do you think if --</p> <p>3 Well, let me ask you this: Do you -- do</p> <p>4 you --</p> <p>5 You don't have an opinion on whether</p> <p>6 chi-squared or Fisher's exact is the appropriate</p> <p>7 methodology for deriving a p-value; correct?</p> <p>8 A. Well I could tell you what --</p> <p>9 Q. In the McGovern study. And I'm just asking</p> <p>10 you about your report, I'm not interested in your</p> <p>11 thoughts on it.</p> <p>12 In your report you don't opine on the</p> <p>13 appropriateness --</p> <p>14 A. I do not o --</p> <p>15 Q. -- of using chi-squared --</p> <p>16 A. I have not opined upon exact test versus</p> <p>17 chi-square.</p> <p>18 Q. Okay. And you express no opinion on the</p> <p>19 appropriateness of the use of chi-squared in</p> <p>20 connection with McGovern.</p> <p>21 A. I did not opine in my report.</p> <p>22 Q. You got to wait until I'm finished --</p> <p>23 A. I'm sorry.</p> <p>24 Q. -- so we're not talking over each other.</p> <p>25 Okay.</p>	<p style="text-align: right;">Page 220</p> <p>1 way or another.</p> <p>2 A. Not on a univariate.</p> <p>3 Q. And you didn't take that into account in</p> <p>4 conjunction with your opinions on what is a confounder</p> <p>5 in connection with McGovern and what's not; correct?</p> <p>6 A. I didn't take what into account?</p> <p>7 Q. Whether any of these changes, if you added</p> <p>8 them up, had a p-value of one.</p> <p>9 A. That's not what we're talking about.</p> <p>10 It's --</p> <p>11 I'm sorry, forgive me. Your statement is a</p> <p>12 misstatement. Perhaps you should ask your question</p> <p>13 again.</p> <p>14 Q. Okay. You didn't, in connection with</p> <p>15 deciding whether something was a confounder, take into</p> <p>16 account the strength of association or the p-value;</p> <p>17 correct?</p> <p>18 A. Did I?</p> <p>19 Q. Yes.</p> <p>20 A. I was not looking at p-values. I think I</p> <p>21 was not looking at p-values. I was largely looking at</p> <p>22 the evidence indicating that there were associations.</p> <p>23 Q. Right. You were using --</p> <p>24 You were reading stuff and using your</p> <p>25 scientific judgment; correct?</p>
<p style="text-align: right;">Page 219</p> <p>1 And what is your view of the importance of</p> <p>2 establishing a p-value in connection with an</p> <p>3 epidemiological undertaking?</p> <p>4 A. I think it is a useful guiding datum. It</p> <p>5 gives you some sense of what is going on, but it also</p> <p>6 has a certain quality of subjectiveness.</p> <p>7 Q. Okay. So if something falls just below or</p> <p>8 just above the known p-value of .05, that's not the</p> <p>9 end of the inquiry is your -- is your view.</p> <p>10 A. I believe that that is not the end of one's</p> <p>11 inquiry.</p> <p>12 Q. Okay. So something can have a causal</p> <p>13 connection even though the p-value is less than .05;</p> <p>14 correct?</p> <p>15 A. You mean more than.</p> <p>16 Q. I'm sorry, more than .05.</p> <p>17 A. Yes. And something can be a confounder even</p> <p>18 when its association on a univariate level is greater</p> <p>19 than p equals .05.</p> <p>20 Q. Okay. What if it's one?</p> <p>21 A. What if it's p equals one?</p> <p>22 Q. Uh-huh. Can it be a confounder?</p> <p>23 A. I don't have an answer to that question.</p> <p>24 Probably not, but I don't know.</p> <p>25 Q. Okay. You don't have an opinion on that one</p>	<p style="text-align: right;">Page 221</p> <p>1 A. And my knowledge, yes.</p> <p>2 Q. Okay. Because, as we talked about earlier</p> <p>3 in the day, there's an element of epidemiology that</p> <p>4 involves scientific judgment; correct?</p> <p>5 A. I think scientific judgment is an important</p> <p>6 thing, yes.</p> <p>7 Q. Okay. And that's what you did here in</p> <p>8 conjunction with deciding what you thought was a</p> <p>9 confounder and what you thought wasn't a confounder;</p> <p>10 correct?</p> <p>11 A. It was part of what I did.</p> <p>12 Q. I'd like to direct your attention to page 11</p> <p>13 of your report starting under the heading "The</p> <p>14 McGovern Study: Sources of Confounding and Systematic</p> <p>15 Bias."</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And in paragraph 27 you talk about</p> <p>18 Gillson and Lowdon, that "...the Northumbria</p> <p>19 Healthcare Trust was regularly informed by the Health</p> <p>20 Protection Agency during 2008 and 2009 that it was 'a</p> <p>21 high outlier for SSI.'" Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. Do you know whether it was a high outlier</p> <p>24 for deep joint infections?</p> <p>25 A. I understood that to be what they were</p>

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<p style="text-align: right;">Page 222</p> <p>1 talking about.</p> <p>2 Q. Based on what?</p> <p>3 A. The focus of the Gillson and Lowdon paper.</p> <p>4 But maybe I overstate it. I'm happy to look again.</p> <p>5 It's clearly within the orthopedic</p> <p>6 department. I don't know whether they specifically</p> <p>7 note -- they say that there was a certain criteria</p> <p>8 which included --</p> <p>9 Well my initial read here does not</p> <p>10 specifically differentiate the types of infections.</p> <p>11 Q. Okay. You don't know whether the</p> <p>12 Northumbria Healthcare Trust was a high outlier for</p> <p>13 deep joint infections; do you, sir?</p> <p>14 A. No, not specifically. I guess I do not.</p> <p>15 Q. Okay. And you say, "This was confirmed by</p> <p>16 Dr. Reed in his deposition." So you relied on Dr.</p> <p>17 Reed for support for that statement about Northumbria</p> <p>18 being a high outlier for SSI; correct?</p> <p>19 A. I guess I did, yes.</p> <p>20 Q. Okay. You also know that Dr. Reed testified</p> <p>21 that he felt that other hospitals in the trust were</p> <p>22 underreporting.</p> <p>23 A. I read that.</p> <p>24 Q. Okay. But you didn't rely on that; did you,</p> <p>25 sir?</p>	<p style="text-align: right;">Page 224</p> <p>1 A. I did.</p> <p>2 Q. And you say, "As noted above, appropriate</p> <p>3 SSI data were available for 9 months from October '07</p> <p>4 to June '08, but they were excluded from the McGovern</p> <p>5 report." Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. You're aware that it wasn't until</p> <p>8 July of 2008 that there was a robust surveillance and</p> <p>9 reporting of infections at Wansbeck; correct?</p> <p>10 MR. GORDON: Object to the form of the</p> <p>11 question.</p> <p>12 A. I -- I have seen conflicting information</p> <p>13 about when --</p> <p>14 I've seen information from Dr. Reed's</p> <p>15 depositions and I've seen stuff from the Gillson</p> <p>16 paper, and I don't know what date it started. I think</p> <p>17 I understand that much of the data that comprise the</p> <p>18 McGovern 16/Albrecht 10 were compiled -- some of it</p> <p>19 was compiled ongoing and some of it was retrospective,</p> <p>20 and I don't know which was which, so I don't know when</p> <p>21 the evaluations really began.</p> <p>22 Q. Okay. Without having evidence to know</p> <p>23 whether Dr. Reed was correct that there wasn't</p> <p>24 complete data reporting until July 2008, you still</p> <p>25 felt comfortable opining in this case that there was</p>
<p style="text-align: right;">Page 223</p> <p>1 A. I didn't have any evidence of that.</p> <p>2 Q. Okay. Did you do any investigation as to</p> <p>3 whether there was underreporting going on by other</p> <p>4 hospitals in the U.K.?</p> <p>5 A. I only know that -- that this hospital was</p> <p>6 reporting much higher than the national rates. I've</p> <p>7 looked at some data on that.</p> <p>8 Q. Okay. Did you do an investigation --</p> <p>9 Can you answer my question? Did you do an</p> <p>10 investigation as to whether Dr. Reed was correct in</p> <p>11 his statement that there was underreporting going on</p> <p>12 at other hospitals during this time period?</p> <p>13 A. I did no such investigation.</p> <p>14 Q. You also -- I take it paragraph 28 is --</p> <p>15 You're relying on Dr. Holford for the</p> <p>16 statements and conclusions in paragraph 28 in your</p> <p>17 report?</p> <p>18 A. Yes, that's correct.</p> <p>19 Q. Okay. And if he's wrong, you're wrong;</p> <p>20 right?</p> <p>21 A. If he's wrong, I'd have to revisit it. Yes.</p> <p>22 Q. Okay. And then in paragraph 29 you say,</p> <p>23 "The analysis by Dr. Holford raises another concern,</p> <p>24 the possibility that the data included in the McGovern</p> <p>25 study had been 'cherry-picked'." Do you see that?</p>	<p style="text-align: right;">Page 225</p> <p>1 cherry-picking and manipulation with respect to the</p> <p>2 start date; correct, sir?</p> <p>3 MR. GORDON: Object to the form of --</p> <p>4 A. I -- I didn't say --</p> <p>5 MR. GORDON: -- the question.</p> <p>6 A. -- that there was cherry-picking, I said</p> <p>7 that the possibility is there based upon the fact that</p> <p>8 there were these data for nine months. And I believe</p> <p>9 I have seen from some deposition exhibits</p> <p>10 prepublication figures, graphs, which suggest a number</p> <p>11 of different start dates for this series of cases, one</p> <p>12 which began in September rather than in July, which</p> <p>13 makes me think that the start date was subject to some</p> <p>14 manipulation or option.</p> <p>15 Q. Well those were start dates with respect to</p> <p>16 the SS -- SSI bundle. I'm talking about robust</p> <p>17 reporting with respect to deep joint infections in</p> <p>18 knees and hips. You have no -- you have no evidence</p> <p>19 to suggest that Dr. Reed was lying when he said that</p> <p>20 the reason they started in July of '08 was because</p> <p>21 that was when they felt there was full and robust</p> <p>22 reporting available.</p> <p>23 MR. GORDON: Object to the --</p> <p>24 Q. Is that right?</p> <p>25 MR. GORDON: Object to the form of the</p>

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<p style="text-align: right;">Page 226</p> <p>1 question, move to strike counsel's preamble, and 2 misstates and mischaracterizes the evidence. 3 MS. CONLIN: You may answer. 4 A. I -- I have no reason to believe that Dr. 5 Reed was lying. 6 Q. Okay. And you say, in connection with 7 paragraph 29, it suggests the possibility of data 8 manipulation. 9 A. Uh-huh. Yes. 10 Q. And again, data manipulation by the authors 11 of the McGovern study? 12 A. Ultimately, yes. 13 Q. Okay. So assuming that Dr. Reed was not 14 lying under oath when he said the reason why we 15 started in July of '08 was because that's when we had 16 full reporting, what is the data manipulation that 17 you're referencing there? 18 MR. GORDON: Object to the form of the 19 question, incomplete hypothetical, assumes facts not 20 in evidence. 21 A. I -- I -- I have seen some earlier work that 22 I think came from Mr. Albrecht, but I'm not certain, 23 which suggested a different starting date for the 24 analysis which comprises the McGovern study, and it 25 was not July but I think it was the following</p>	<p style="text-align: right;">Page 228</p> <p>1 A. I think that he has a master's degree from 2 the University of Minnesota in statistics. 3 Q. And he's a professor there? 4 A. I didn't know that. 5 MR. GORDON: Object to the form of the 6 question, assumes facts not in evidence. 7 Q. Are you -- are you -- are -- 8 Is it Mark Albrecht who engaged in data 9 manipulation? You referenced him. 10 A. I don't know. 11 MR. GORDON: Object to the form of the 12 question. 13 Q. Okay. 14 A. I don't know. 15 Q. All right. Was it Dr. Reed, Dr. -- 16 How about Dr. Belani? 17 MR. GORDON: Same objection. 18 A. I don't know. 19 Q. Okay. But as you sit here, you don't have 20 any evidence to refute Dr. Reed's sworn testimony that 21 the reason they started in July of '08 was because 22 that was the first time they felt like they had full 23 implementation of surveillance and reporting of DJIs 24 in knees and hips. 25 MR. GORDON: Object to the form of the</p>
<p style="text-align: right;">Page 227</p> <p>1 September, and so I think that there was some ability 2 to alter the starting date. That's the first piece. 3 The second piece, it may be entirely coincidental, but 4 I think that the Holford analysis of statistical 5 significant starting dates is very interesting because 6 had it started September instead of July, then the 7 effect of switching from Bair Hugger to Hot Dog would 8 not have been statistically significant; July was 9 statistically significant; June and August were not. 10 It's -- 11 It may be just coincidence, I don't know, 12 that's why I say it raises the possibility. 13 Q. Well don't you think you need some evidence 14 if you're going to accuse the authors of the McGovern 15 study of scientific fraud? 16 MR. GORDON: Object to the form of the 17 question. 18 A. I -- I was being very careful not to accuse 19 anybody. 20 Q. Okay. Then -- 21 A. I said -- 22 Q. -- accuse them of data manipulation. 23 A. I said it raises the concerns of that. 24 Q. Do you know who Mark Albrecht is, what his 25 credentials are?</p>	<p style="text-align: right;">Page 229</p> <p>1 question. 2 A. I -- I earlier said that there were earlier 3 efforts at the analysis which started on different 4 dates. The information about when the surveillance 5 began I assume didn't change over time, and so it 6 suggests that the analysis was changed over time. 7 That's all I'm saying. 8 Q. And -- and can you answer my question now? 9 MS. CONLIN: Can you read it back, Mr. Court 10 Reporter. 11 (Record read by the court reporter.) 12 MS. CONLIN: You may answer. 13 MR. GORDON: Same objection. 14 A. I have no basis to refute his statement, but 15 I have reason to question it. 16 Q. Okay. And that's the same individual that 17 you relied on repeatedly throughout your expert 18 report; correct? 19 MR. GORDON: Object to the form of the 20 question. 21 A. I quoted him a number of times, yes. 22 Q. Thank you. 23 MS. CONLIN: Why don't we take a break here. 24 THE REPORTER: Off the record, please. 25 (Recess taken.)</p>

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<p style="text-align: right;">Page 230</p> <p>1 (Exhibit 28 was marked for 2 identification.) 3 BY MS. CONLIN: 4 Q. I've handed you, sir, what's been marked as 5 Borak Exhibit 28, which is another excerpt out of day 6 two of the deposition of Dr. McGovern. You can take a 7 look on the back page of this excerpt exhibit and 8 direct your attention down to page 408. At line 17 it 9 says: 10 "Are you aware of any paper that is 11 adequately powered that shows a change from a standard 12 adhesive dressing to a jubilee dressing would 13 statistically significant -- significantly alter 14 infection rates among arthroplasties?" Do you see 15 that? 16 A. I do. 17 Q. And he says, "I am not aware of any such 18 paper." Do you see that? 19 A. I do. 20 Q. Do you have any reason to dispute that? 21 MR. GORDON: To dispute what? 22 A. That he said that? 23 Q. I'll rephrase it. 24 Are you aware of any paper that is 25 adequately powered that shows a change from the</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Okay. Directing your attention back to your 2 report, page 21, did you find -- based on your review 3 of the record, did you find consistency among the 4 bubble and particle studies as it relates to use of 5 the Bair Hugger increasing particulates or bubbles 6 over the surgical site? 7 A. I thought there was inconsistency, but I did 8 not do a systematic review and I did not offer an 9 opinion on that. 10 Q. Okay. So you don't know. 11 We looked at, for example, the corporate 12 representative Al Van Duren's testimony this morning 13 that said that every single study out there shows an 14 increase in absolute numbers of particles when Bair 15 Hugger is in use. You don't have any reason to 16 dispute that; do you? 17 A. I -- I have read other papers, I think 18 there's one by somebody named Oguz, who found no 19 evidence of increase. I -- I'm -- 20 But it's not an area that I have 21 particularly taken on for myself, and I don't have 22 expertise in that area. 23 Q. Okay. So you don't have any reason to 24 dispute at least Al Van Duren's testimony as a 25 corporate representative for 3M.</p>
<p style="text-align: right;">Page 231</p> <p>1 standard adhesive addressing to a jubilee dressing 2 that would statistically significantly alter infection 3 rates among arthroplasties? 4 A. That was the question that was posed. 5 Q. Yes. 6 A. Yes. And you're asking do I have -- 7 And his answer was "I am not aware of any 8 such paper." 9 Q. Are you aware of any? 10 A. I have not, in depth, read about the jubilee 11 dressing. 12 Q. Okay. If you look on page 409 and at line 13 four: 14 "Question: Are you aware of any evidence 15 that is statistically significant that suggests the 16 use of MSSA screening significantly impacts the rate 17 of deep joint infections among patients? 18 "Answer: I'm not aware of any such papers." 19 Do you see that? 20 A. I do. 21 Q. Are you aware of any such papers? 22 A. I thought I was. Perhaps I'm not. I had 23 Dr. Reed's statement which I had referred to, I think, 24 specifically. I don't remember whether I have one 25 that specifically addresses joint infection.</p>	<p style="text-align: right;">Page 233</p> <p>1 A. I would have no basis to dispute the 2 corporate representative's opinion. 3 Q. Now I'd like to direct your attention to -- 4 You understand that each of the authors of 5 the McGovern study continue to stand behind the 6 conclusions in that study; right, sir? 7 MR. GORDON: Object to the form of the 8 question. 9 A. I'm not sure which conclusions. What? 10 Q. That the study is valid and that there's a 11 significant increased risk of a deep joint infection 12 by use of the Bair Hugger. 13 MR. GORDON: Object to the form of the 14 question and mis -- 15 A. I think each of them -- 16 MR. GORDON: Let me finish my objection. 17 THE WITNESS: Sorry. 18 MR. GORDON: -- assumes facts not in 19 evidence, mischaracterizes the evidence. 20 MS. CONLIN: You may answer. 21 A. I believe each of the authors has said that 22 this shows an association, not a causation, so it 23 agreed with what you just said in your question. 24 Q. Okay. You would agree that each of the 25 authors, when questioned under oath, stand by the</p>

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<p style="text-align: right;">Page 234</p> <p>1 veracity and the validity of the findings as expressed 2 in the McGovern paper; correct? 3 A. I think that they indicated that the numbers 4 were not correct. Now when you say "veracity and 5 validity," I'm not sure how to deal with that if the 6 numbers are not correct. 7 Q. Okay. Let me state it a different way 8 because I don't want to drag you through all the 9 transcripts. 10 You'd agree with me that each of the authors 11 testified under oath that they stand by the 12 conclusions in the McGovern paper that they found a 13 3.8 increased risk of infection when the Bair Hugger 14 was used over the Hot Dog; correct? 15 A. My impress -- 16 MR. GORDON: Object to form -- object to -- 17 Well same objections as the last one. 18 A. Just for the record, I apologize to 19 everybody for stepping on you. It's late in the day 20 and I'm losing my control. 21 My understanding was that one or more of the 22 authors agreed that the numbers were not correct, and 23 if the numbers were changed according to what was 24 talked about in the depositions, then the 3.8 number 25 would not be correct. That's my understanding.</p>	<p style="text-align: right;">Page 236</p> <p>1 conclusion in the paper. 2 MS. CONLIN: Thank you. Mark this, please. 3 (Exhibit 29 was marked for 4 identification.) 5 BY MS. CONLIN: 6 Q. I've handed you what's been marked as 7 Deposition Exhibit 29, Borak Deposition Exhibit 29 -- 8 MR. GORDON: Is that 29 or 30? Oh, you used 9 a premarked. I'm sorry. Go ahead. 10 Doesn't this deal with Nachtsheim? 11 MS. CONLIN: Yeah. 12 Q. Let me start over again. 13 You've been handed, sir, what's been marked 14 as Borak Deposition Exhibit 29, which is an excerpt 15 out of the Professor Nachtsheim deposition, one of 16 the depositions that you relied on; correct? 17 A. Yes. 18 Q. Do you know whether Professor -- 19 Do you have any reason to dispute the 20 honesty and scientific credibility of Professor 21 Nachtsheim? 22 A. I have no particular reason to do that. 23 Q. Okay. And if you look at internal page 350 24 of this exhibit -- 25 Do you have it there?</p>
<p style="text-align: right;">Page 235</p> <p>1 Q. Okay. But they -- 2 Even those who said there might have been 3 one more infection said there would still be a 4 significant odds risk ratio; correct? 5 A. I don't think -- 6 MR. GORDON: Same objections. 7 Q. Well let me ask it a different way. 8 Did you see any of them in their depositions 9 under oath say that the findings that they reached in 10 McGovern that use of the Bair Hugger is associated 11 with an increased risk of deep joint infection was 12 wrong? 13 A. I saw some of them say that the numbers 14 included in the publications -- 15 Q. I'm not asking about that. 16 A. -- were wrong. 17 Q. I'm asking about the conclusions in the 18 paper. Can you answer my question? 19 A. Well, but if the conclusion is, as you 20 suggested before, an odds ratio of 3.8 -- 21 Q. That's not what I asked. 22 MS. CONLIN: Mr. Stirewalt, can you read it 23 back, please. 24 (Record read by the court reporter.) 25 A. I did not see any of them withdraw the</p>	<p style="text-align: right;">Page 237</p> <p>1 A. I see it. 2 Q. -- the question is: 3 "Question: And do you -- And you continue 4 to stand by the results of the observational 5 studies -- 6 "Yes. 7 -- "in the McGovern publication? 8 "I do." 9 Do you see that? 10 A. I do see that. 11 Q. Okay. Do you have any reason to suspect 12 that Professor Nachtsheim engaged in data 13 manipulation? 14 A. I have no reason to suggest that he did 15 that. 16 Q. Okay. And have you seen anything that would 17 suggest that Professor Nachtsheim would allow 18 somebody to manipulate data in connection with a study 19 that he was on? 20 A. I -- I have no ability to comment on that. 21 Q. Finally, if we can look, sir, at your 22 summary, which is contained on page 22. 23 A. Yes. 24 Q. And you've got a summary, "Following is a 25 list of my opinions, all to a reasonable degree of</p>

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<p style="text-align: right;">Page 238</p> <p>1 medical and scientific certainty." Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. You'd agree with me that each of your</p> <p>4 conclusions stated there rely on a finding that the</p> <p>5 McGovern study is not valid; correct?</p> <p>6 MR. GORDON: Object to the form of the</p> <p>7 question.</p> <p>8 A. Not valid or wrong. Perhaps that's the same</p> <p>9 thing.</p> <p>10 Q. Okay. But you'd agree with me if -- if the</p> <p>11 McGovern paper is legitimate, if the findings in there</p> <p>12 are correct, then none of your opinions as expressed</p> <p>13 in your summary have merit; correct?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 A. The first four are probably -- a through d</p> <p>17 probably follow from the point that you've just made.</p> <p>18 The issue is whether the McGovern paper is or is not a</p> <p>19 legitimate basis of evidence.</p> <p>20 Q. Well e relies -- your conclusion in e also</p> <p>21 require -- relies on McGovern being invalid; correct?</p> <p>22 A. No, no, it's also on the current Augustine</p> <p>23 being invalid.</p> <p>24 Q. Okay. Fair enough. But your -- okay.</p> <p>25 So 74e, if either McGovern or the new</p>	<p style="text-align: right;">Page 240</p> <p>1 Environment and Disease: Association or Causation?"</p> <p>2 Correct?</p> <p>3 A. Correct.</p> <p>4 Q. And you've actually cited this publication</p> <p>5 in connection with your work; correct?</p> <p>6 A. Correct.</p> <p>7 Q. I'd like to direct your attention to the</p> <p>8 last page, page 12.</p> <p>9 A. Yes.</p> <p>10 Q. Second-to-last paragraph, "All scientific</p> <p>11 work is incomplete -- whether it be observational or</p> <p>12 experimental. All scientific work is liable to be</p> <p>13 upset or modified by advancing knowledge. That does</p> <p>14 not confer upon us a freedom to ignore the knowledge</p> <p>15 we already have, or to postpone the action that it</p> <p>16 appears to demand at a given time." Do you see that?</p> <p>17 A. I do.</p> <p>18 Q. Do you agree with that statement?</p> <p>19 A. I think it's very reasonable.</p> <p>20 MS. CONLIN: Okay. No further questions.</p> <p>21 THE REPORTER: Let's go off the record a</p> <p>22 moment, please.</p> <p>23 REDIRECT EXAMINATION</p> <p>24 BY MR. GORDON:</p> <p>25 Q. Dr. Borak, if I could ask you to just pull</p>
<p style="text-align: right;">Page 239</p> <p>1 Augustine publication or both are scientifically</p> <p>2 valid, then your opinion as expressed in 74e of your</p> <p>3 report also wouldn't hold up; correct?</p> <p>4 A. If --</p> <p>5 Yes.</p> <p>6 Q. Okay. And same with respect to your final</p> <p>7 conclusion, 74f, "Because there is insufficient</p> <p>8 evidence that there's a significant association</p> <p>9 between the Bair Hugger and deep joint infections,</p> <p>10 Bair Hugger does not represent a substantial</p> <p>11 contributing cause of deep joint infections."</p> <p>12 Correct?</p> <p>13 A. Yes.</p> <p>14 MS. CONLIN: Okay. Let me check my notes.</p> <p>15 I think we're done.</p> <p>16 THE REPORTER: Off the record, please.</p> <p>17 (Recess taken.)</p> <p>18 (Exhibit 30 was marked for</p> <p>19 identification.)</p> <p>20 BY MS. CONLIN:</p> <p>21 Q. I've handed you, sir, what's been --</p> <p>22 A. Can I first --</p> <p>23 Yes. Please go ahead. I'm sorry.</p> <p>24 Q. -- what's been marked as Borak Exhibit 30,</p> <p>25 which is the Bradford-Hill article entitled "The</p>	<p style="text-align: right;">Page 241</p> <p>1 out Exhibit 27.</p> <p>2 MS. CONLIN: Which exhibit is that, Mr.</p> <p>3 Gordon?</p> <p>4 MR. GORDON: It is a piece of testimony from</p> <p>5 the first day of Dr. McGovern.</p> <p>6 A. Yes, sir.</p> <p>7 Q. And if you want to turn to page 115,</p> <p>8 transcript page 115.</p> <p>9 A. Yes, sir.</p> <p>10 Q. And that -- the first question and answer</p> <p>11 that -- the question and answer that Ms. Conlin asked</p> <p>12 you about.</p> <p>13 A. "...do you believe it would have been</p> <p>14 reasonable" --</p> <p>15 Yes, I see that.</p> <p>16 Q. Okay. And you said you also read the --</p> <p>17 You were reading to yourself the -- the</p> <p>18 second question. Could you read that -- the question</p> <p>19 and answer that you read to yourself.</p> <p>20 A. The paragraph that starts "We -- if we have</p> <p>21 said that we believe, or think" --</p> <p>22 Q. Yeah. In fact, you know what? For context,</p> <p>23 would you mind just reading both questions and</p> <p>24 answers, the one that Ms. Conlin asked you and then</p> <p>25 the -- then the next one.</p>

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<p style="text-align: right;">Page 242</p> <p>1 A. The question is: 2 "Based on the evidence that you had, do you 3 believe it would have been reasonable for your paper 4 to imply a causal connection? 5 "Answer: If properly qualified, yes. 6 "Question: What would the proper 7 qualifications be? 8 "Answer: We -- if we had said that we 9 believe, or think, that there is evidence that 10 suggests that forced-air warming has an influence on 11 infection, but that we recognize there are confounding 12 factors, then that implication is tempered with the 13 recognition that there are other effects that could be 14 at play." 15 Q. Okay. You can put that -- thank you, you 16 can put that aside. 17 And then I just want to pull -- have you 18 pull out Exhibit 22, I think, the Hickson paper, and I 19 will direct you to the same page Ms. Conlin read from, 20 page 186, in that second full paragraph there which 21 is -- that's -- that's the one she read from where 22 she -- where it said -- where this paper -- Dr. Reed 23 is one of the authors, "Although there is a large body 24 of evidence for the use of prophylactic antibiotics in 25 primary hip and knee arthroplasty, there is no clear</p>	<p style="text-align: right;">Page 244</p> <p>1 doses or prolonged courses of treatment result in 2 fewer SSIs, studies have shown that this dose may be 3 inadequate for patients weighing over 70 kilograms." 4 Q. Okay. Do you have any disagree -- reason to 5 disagree with Dr. Reed's statements about the efficacy 6 of Teicoplanin? 7 A. I have no reason to disagree with that. 8 Q. And what was the antibiotic that was added 9 to the prophylactic antibiotic regimen prior to the 10 switchover to the Hot Dog in the McGovern paper? 11 A. Teicoplanin was added to a reduced 12 Gentamicin dose. 13 Q. Okay. Do you recall any discussion in Mr. 14 Albrecht's testimony about the statistical comparison 15 between a time period during the Bair Hugger-only 16 cohort where the same antibiotics and same 17 thromboprophylaxis was used as was used in the Hot Dog 18 period? 19 A. I recall that there was such a discussion. 20 Q. And do you recall whether -- what -- what 21 Mr. Albrecht had to say about what -- about whether 22 there was or was not any statistically significant 23 difference in the infection rate in -- in those two 24 periods? 25 MS. CONLIN: Objection, misstates the record</p>
<p style="text-align: right;">Page 243</p> <p>1 benefit to using one particular agent/regimen." 2 A. Yes. 3 Q. Do you see that? 4 Okay. And on the same page does it discuss 5 specifically the regimen of Gentamicin only? 6 A. It reads, "There is no evidence for the use 7 of systematic -- systemic gentamicin as prophylaxis in 8 primary elective total hip arthroplasty and total knee 9 arthroplasty surgery." 10 Q. Okay. And do you have any reason to 11 disagree with Dr. Reed's conclusion that there was no 12 evidence for the use of system -- systemic Gentamicin 13 as prophylaxis in primary elective THA and TKA 14 surgery? 15 A. I -- I have no reason to disagree. 16 Q. And what was the antibiotic prophylaxis that 17 was being used at the beginning of the Bair Hugger- 18 only period? 19 A. Gentamicin only. 20 Q. Okay. And does it say anything about the 21 Teicoplanin? 22 A. It reads, "Four randomised controlled trials 23 provide strong evidence for the use of a single dose 24 of 400 milligrams of teicoplanin at induction. 25 Although there is no evidence to suggest that higher</p>	<p style="text-align: right;">Page 245</p> <p>1 and assumes facts not in evidence. 2 A. I -- I believe he reported that there was no 3 significant difference. 4 Q. And did you read any testimony from Dr. Reed 5 about that same comparison; in other words, the -- the 6 period during the Bair Hugger-only cohort when it was 7 the same antibiotics and same thromboprophylaxis as 8 the Hot Dog period? 9 A. I think I do remember it. 10 Q. Do you recall what Dr. Reed testified 11 about -- 12 A. I'm sorry. 13 Q. -- in that comparison? 14 A. I -- I -- I, by now, cannot distinguish 15 between the two, al -- but I -- I -- 16 I don't remember specifically. I'm sorry. 17 Q. By -- by "the two," do you mean Reed and 18 Albrecht or Reed and McGovern? 19 A. Yes, Reed and McGovern. 20 MR. GORDON: Okay. No further question. 21 MS. CONLIN: One followup. 22 RE CROSS EXAMINATION 23 BY MS. CONLIN: 24 Q. With respect to the Hickson study and the 25 statements from that study that you just read, those</p>

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<p style="text-align: right;">Page 246</p> <p>1 were for SSIs, not necessarily deep joint infections; 2 correct? 3 MR. GORDON: Object to the form of the 4 question. Ask you to read the -- the whole paper if 5 she -- if you want to go there. 6 MS. CONLIN: No. I'm asking him with 7 respect to the specific statement that you just had 8 him read into the record. 9 Q. It was directed to SSIs and not specifically 10 deep joint infections; correct? 11 A. It was specifically hip and knee 12 arthroplasty, but I do not see a distinction of joint 13 versus other infections. 14 Q. Right. And the language that Mr. Gordon 15 just had you read related to SSIs; correct? 16 A. Yes, I think so. 17 MS. CONLIN: No further questions. 18 RE-REDIRECT EXAMINATION 19 BY MR. GORDON: 20 Q. Unfortunately, we're going to have to go 21 back to the Hickson paper then, Exhibit 22. Go 22 back -- go back to page 186 and the statement that -- 23 We'll go back to the original statement that 24 Ms. Conlin read from that. "Although there is a large 25 body of evidence for the use of prophylactic</p>	<p style="text-align: right;">Page 248</p> <p>1 A. You want me to go back to what? 2 Q. Read the statement that Mr. Gordon read you 3 out of the Hickson paper. 4 A. Out of the Hickson paper. 5 Q. Yes, prior to the time he just showed you 6 that one. 7 A. I -- I'm getting confused and it's late. 8 Would you point to which paragraph you would like me 9 to look at. 10 MS. CONLIN: Which page and paragraph was 11 it, Mr. Gordon? 12 MR. GORDON: One fif -- 13 One eighty-six, second full paragraph. 14 MS. CONLIN: No, the first time you went 15 over it with him. 16 MR. GORDON: Oh, earlier? 17 MS. CONLIN: Yes. That was early -- 18 MR. GORDON: Same page, same page, and it 19 was on the other side of the -- there was -- 20 A. Oh, the Gentamicin and the Teicoplanin 21 questions? 22 Q. Yes. 23 A. And what is the question you would like me 24 to respond to? 25 Q. You know what? Let's just let the record</p>
<p style="text-align: right;">Page 247</p> <p>1 antibiotics in primary hip and knee arthroplasty, 2 there is no clear benefit to using one particular 3 agent/regimen." 4 Could you read the next sentence in that 5 paragraph. 6 A. "This is unsurprising, given that prosthetic 7 joint infection is a rare event and that a randomised 8 study would need over 3000 patients per group in order 9 to demonstrate a reduction in the rate of infection 10 from 2 percent to 1 percent, with a power of 90 11 percent at the 95 percent confidence interval." 12 Q. Do you know what "PJI" refers to there? 13 A. Prosthetic joint infection. 14 Q. Okay. 15 A. That would lead me to correct my response 16 earlier. This suggests that this was specifically 17 concerned with prosthetic joint infections. 18 MR. GORDON: Thank you. Nothing further. 19 RE-RECROSS EXAMINATION 20 BY MS. CONLIN: 21 Q. Can you go back to the language that Mr. 22 Gordon quoted you during his first examination of you 23 and read that back into the record. 24 A. Are you speaking to me? 25 Q. Yes.</p>	<p style="text-align: right;">Page 249</p> <p>1 speak for itself. We'll be done. 2 MS. CONLIN: I have no further questions. 3 THE REPORTER: Off the record, please. 4 (Deposition concluded.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

RICHARD G. STIREWALT
Registered Professional Reporter
Notary Public

Notary Public

EXHIBIT DX5

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK



■ ARTHROPLASTY

Forced-air warming and ultra-clean ventilation do not mix

AN INVESTIGATION OF THEATRE VENTILATION, PATIENT WARMING AND JOINT REPLACEMENT INFECTION IN ORTHOPAEDICS

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We investigated the capacity of patient warming devices to disrupt the ultra-clean airflow system. We compared the effects of two patient warming technologies, forced-air and conductive fabric, on operating theatre ventilation during simulated hip replacement and lumbar spinal procedures using a mannequin as a patient. Infection data were reviewed to determine whether joint infection rates were associated with the type of patient warming device that was used.

Neutral-buoyancy detergent bubbles were released adjacent to the mannequin's head and at floor level to assess the movement of non-sterile air into the clean airflow over the surgical site. During simulated hip replacement, bubble counts over the surgical site were greater for forced-air than for conductive fabric warming when the anaesthesia/surgery drape was laid down ($p = 0.010$) and at half-height ($p < 0.001$). For lumbar surgery, forced-air warming generated convection currents that mobilised floor air into the surgical site area. Conductive fabric warming had no such effect.

A significant increase in deep joint infection, as demonstrated by an elevated infection odds ratio (3.8, $p = 0.024$), was identified during a period when forced-air warming was used compared to a period when conductive fabric warming was used. Air-free warming is, therefore, recommended over forced-air warming for orthopaedic procedures.

It has been acknowledged that the operating theatre's ventilation system has a critical role in preventing joint infection.¹ Charnley postulated that the 'surgical implant might provide a nidus for the growth of airborne bacteria which ordinarily are accepted as non-pathogenic'.¹ This has been confirmed through animal studies² and a national clinical trial involving over 8000 operations demonstrating the contribution of clean air to the reduction of the rate of infection after arthroplasty.³ Following that report, ultra-clean ventilation became the standard for joint replacement procedures. The system protects the surgical site from airborne contamination through the constant delivery of a downward uniform-velocity (0.3 m/s to 0.5 m/s), highly filtered (> 99.997%) airflow.⁴ However, the performance of ultra-clean ventilation depends critically on airflow volumes and proper temperature gradients. The latter may be disrupted by excess heat released by patient warming devices.

Forced-air warming is now commonly used in operating theatres to ensure normothermia of the patient. The vented airflow from forced-

air warming is released at up to 43°C, which is often 20°C above ambient operating theatre conditions.^{5,6} The release of excess thermal energy can establish temperature gradients that impede the downward flow of ultra-clean air. Reductions in the velocity of downward flow have also been shown to increase the entry of contaminants into the surgical site.⁷ In addition, the release of heat may generate convection currents that rise against the downward airflows, drawing non-sterile floor-level air into the surgical site.

Air-free alternatives, such as conductive fabric warming, have been developed that are comparably effective for the prevention of hypothermia.⁸⁻¹⁴ These offer higher thermal efficiencies than forced-air warming and therefore release only a fraction of the excess heat.⁶ Accordingly, we chose to compare the effects of forced-air and conductive fabric warming on clean airflow patterns over the surgical site in a partial-walled ultra-clean operating theatre during two simulated procedures: a hip replacement with upper-body warming, and a lumbar spinal procedure with lower-body warming. Ventilation airflow patterns were

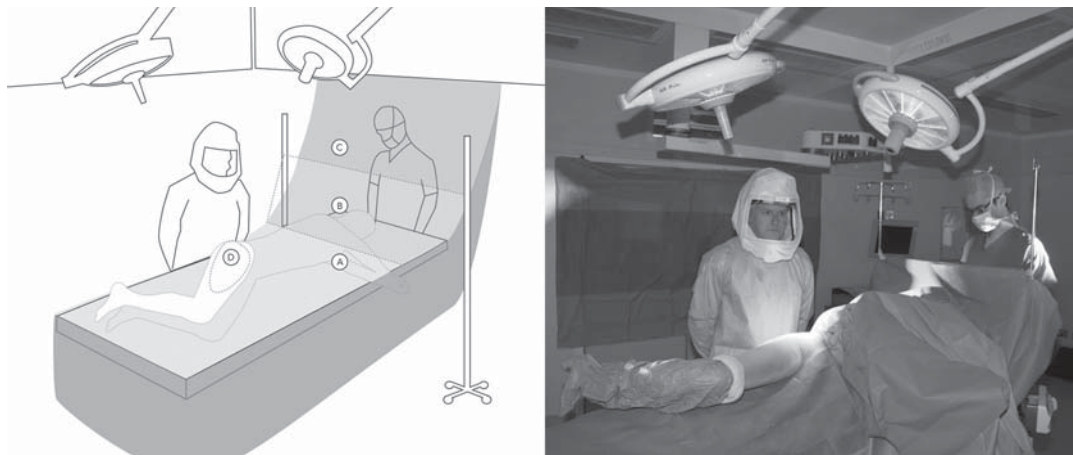


Fig. 1

Diagram (left) and photograph (right) showing the operating theatre set-up for hip replacement with upper-body warming showing surgical drape positions of laid-down (A), half-drape (B) and full-drape (C) and surgical site location (D).

visualised using neutrally buoyant detergent bubbles. In addition, observational data on arthroplasty infection rates were compared for the period each warming device was in clinical use in our hospital.

Materials and Methods

Ultra-clean operating theatre characteristics. Experiments were carried out in a partial-walled ultra-clean operating theatre (ExFlow 90; Howorth, Bolton, United Kingdom) used for orthopaedic and spinal surgery in the United Kingdom. Validation and verification checks according to Hospital Technical Memorandum 2025¹⁵ showed the operating theatre airflows to be within specification and having a mean velocity of 0.44 m/s at a height of 2 m, which exceeds the threshold required by the standard (0.38 m/s). Owing to the location of the theatre preparation room an insignificant airflow imbalance was detected that affected the results of a single-particle entrainment test: entrainment values were 12% at that location, which marginally exceeded the recommended threshold of 10%.

Airflow visualisation procedures. High-intensity lighting was used to illuminate neutrally buoyant detergent bubbles having a diameter of approximately 4 mm (referred to here as 'bubbles'). A SAI bubble generator (SAI Model 5; Sage Action Inc., Ithaca, New York) was used to produce bubbles using a helium-mixed air supply and detergent. The equipment uses a centrifugal classifier to allow only bubbles of neutral buoyancy through the system, with heavier or lighter bubbles discarded. The bubble generator is specifically designed and validated for the visualization of air currents.¹⁶ For photography, a digital camera (EOS 500D; Canon, Reigate, United Kingdom) was used and exposure time set to 0.25 s for time-lapse photography.

Experimental setup. Hip replacement. A mannequin was laid in the lateral position on an operating table and draped with a three-piece disposable draping set (Molnlycke Health Care, Manchester, United Kingdom) in accordance with standard protocols (Fig. 1). The drapes had adhesive edges and all were sealed during draping. A surgeon, dressed in occlusive clothing with head gear (T4; Stryker, Kalamazoo, Michigan), stood motionless in front of the surgical site and an anaesthetist stood at the head of the operating table. At the head end the drape was used to create an anaesthesia screen in one of three positions, either clipped to the ceiling to create a barrier between the surgical site and the anaesthesia area (full-drape); clipped to the intravenous stands and raised 0.75 m above the operating table (half-drape); or laid down over the mannequin's head (laid-down). The upper-body warming treatment was introduced under the drape and was either a torso forced-air blanket (Bair Hugger Model 540; Arizant Healthcare, Eden Prairie, Minnesota) or a torso conductive fabric blanket (Hot Dog Model B110; Augustine Temperature Management, Eden Prairie, Minnesota). The warming devices were powered by standard controllers set to 43°C. Bubbles were introduced at the head/neck of the mannequin to track under-drape resident air movements in the region where the excess heat from patient warming was being released.

Lumbar spinal procedure. The same mannequin was laid in the prone position on the operating table and four drapes were arranged in a square configuration (Molnlycke Health Care) with the screen at full height (Fig. 2). A single surgeon stood motionless next to the surgical site for all experiments. A standard theatre gown and face mask were worn by the surgeon. The lower-body warming treatment was introduced under the drape and was either a lower-body forced-air blanket (Bair Hugger Model 525; Arizant

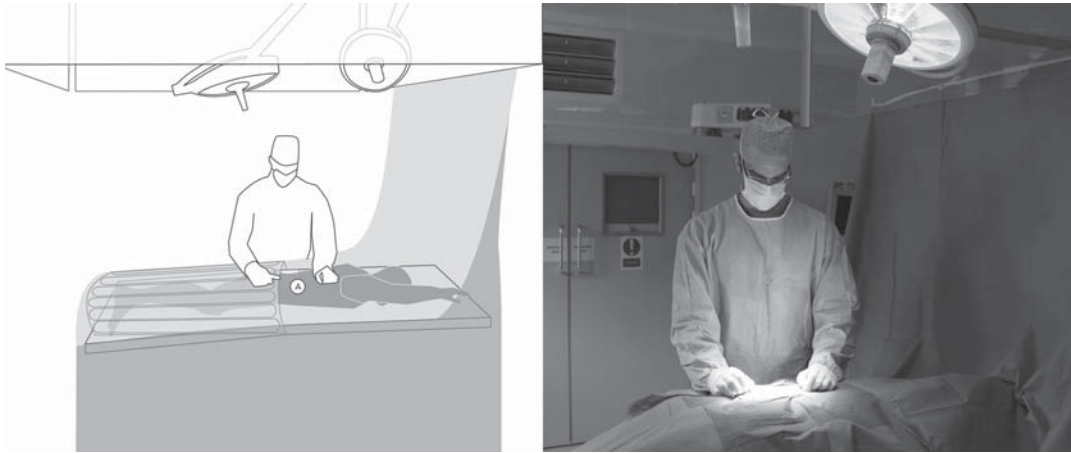


Fig. 2

Diagram (left) and photograph (right) showing the operating theatre set-up for lumbar spinal surgery with lower-body warming and full-drape, showing surgical site location (A).



Fig.3a



Fig.3b

Photographs showing a) the definition of the region where bubble counts were performed over the surgical site for hip replacement with upper-body warming, with bubbles (white streaks) appearing in the photograph for the experimental setup of forced-air warming and half-drape, and b) bubbles exiting the diffuser in still air.

Healthcare) or a lower-body conductive fabric blanket (Hot Dog Model B103; Augustine Temperature Management). The devices were powered by the same controllers as listed above and set to 43°C. Bubbles were introduced at floor level between the surgeon's body and the operating table in the area where the excess heat from patient warming was being released.

Sampling procedures. Hip replacement. Bubble counts over the surgical site were measured using a sequence of five photographs taken at ten-second intervals. The number of bubbles reaching the surgical site was determined by counting the number of bubbles in a 0.5 × 0.5 m region over the surgical site in each photograph (Fig. 3).

Lumbar spinal procedure. A different airflow pattern was observed with the spinal simulation, therefore time-lapse

photography was chosen rather than bubble counts for data presentation. Time-lapse photography also provides directional information on airflow patterns that cannot be easily captured in quantitative data.

Experimental design. Hip replacement. A replicated ($n = 2$) 3^{121} full factorial design was used to assess changes in bubble counts over the surgical site. The experimental factors considered were the anaesthesia/surgery screen: laid-down, half-screen or full-screen; and the patient warming device: conductive fabric or forced-air.

Lumbar spinal procedure. No design was either used or necessary to demonstrate the difference in ventilation performance between forced-air and conductive fabric warming systems.

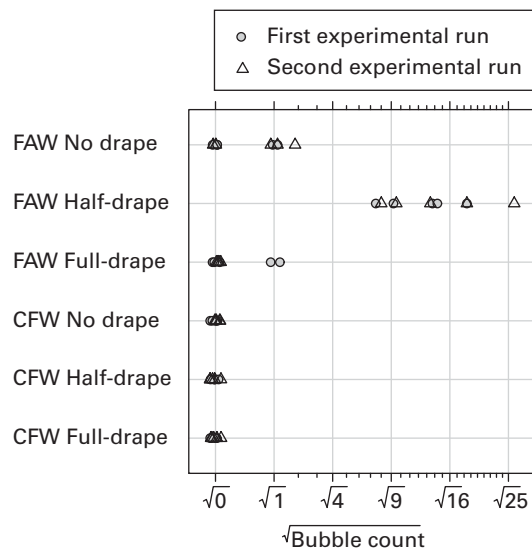


Fig. 4

Chart showing bubble counts over the surgical site for each photograph (data are staggered for clarity). Five photographs were taken for each experimental run (FAW, forced-air warming; CFW, conductive fabric warming).

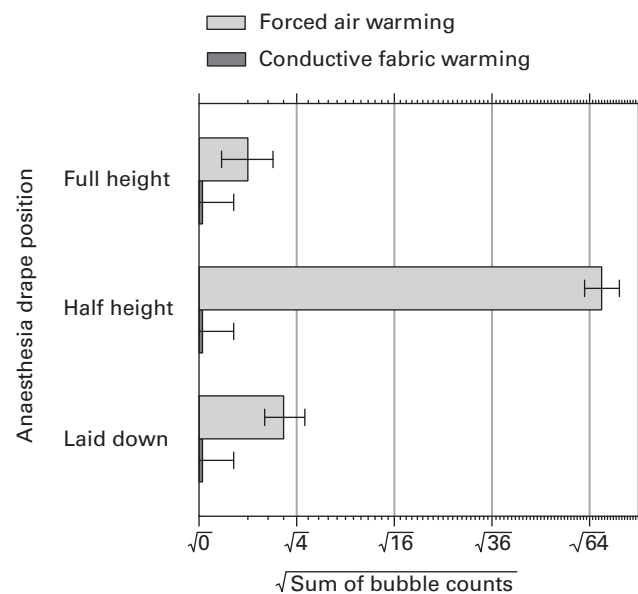


Fig. 5

Bar chart showing the mean bubble count for experimental runs when the bubble counts were summated over the five photographs. Error bars represent the standard error of the mean. Wald tests were used for statistical inference.

Joint infection data. Demographic information on relevant risk factors for surgical site infection (SSI) were collected for primary hip and knee replacement procedures performed at our hospital during a 2.5-year period starting 1 July 2008. Infection was diagnosed by SSI nurses according to English Health Protection Agency criteria for deep infection.¹⁷ In order to standardise the duration of follow-up, only infections presenting within 60 days of surgery were included. Microorganism identification was performed on isolates from septic joints. A transition in patient warming systems from forced-air to conductive fabric was made in all three elective orthopaedic theatres, starting on 1 March 2010 and ending on 1 June 2010. Unfortunately, the prophylactic antibiotic regimen was not constant during the study period. From July 2008 to February 2009, a single dose of gentamicin 4.5 mg/kg was given at induction. In March 2009 this was changed to teicoplanin 400 mg and gentamicin 3 mg/kg. Gentamicin-loaded cement (0.5 g per 40 g mix) was used for both groups. Similarly, the thromboprophylaxis regimen from July 2008 to the end of July 2009 was tinzaparin (Leo Pharma, Princes Risborough, United Kingdom) from day one to day 14 or 28 post-operatively for knee or hip replacement, respectively. From August 2009 to February 2010 rivaroxaban (Bayer PLC, Newbury, United Kingdom) was provided from day one post-operatively, but in February 2010 to the end of the study this reverted to tinzaparin from day one post-operatively.

Statistical analysis. A Poisson regression model was fitted to the hip replacement data having the sum of bubble counts for each experimental run (five photographs) as the

response and the factors identified in the experimental design as predictors. Differences in demographics and comorbidities between the patient warming groups were assessed by analysis of variance (ANOVA) or log-linear contingency table methods. Univariate odds ratios (OR) for the development of joint sepsis were computed using separate logistic regression models for each risk factor. Logistic regression was used to determine mean infection rates and dispersion indices for the periods of forced-air warming, transition and conductive fabric warming. Further details on statistical methods are provided in each table or figure. A p -value < 0.05 was considered statistically significant.

Results

Hip replacement. Bubble counts per photograph show that forced-air warming mobilised under-drape air so that it passed over the anaesthesia/surgery drape and into the surgical site (Fig. 4), but conductive fabric warming did not have a mobilising effect. Further, the position of the drape had a large effect on under-drape air mobilisation for forced-air warming.

Based upon Wald tests, differences in the sum of bubble counts for each experimental run (Fig. 5) were significant between conductive fabric and forced-air warming for the drape configurations of half-drape (0 *versus* 68, $p < 0.001$) and laid-down (0 *versus* 3, $p = 0.010$); differences for full-drape (0 *versus* 1, $p = 0.283$) did not reach statistical significance.

Lumbar spinal procedure. Excess heat from forced-air warming resulted in the development of hot-air convection currents between the surgeon's body and the operating table that transported floor-level air upwards and into the surgical

Table I. Demographics of surgical site infection risk factors by patient warming device (SEM, standard error of the mean)

	Forced-air warming	Conductive fabric warming	p-value*
Mean age (years) (SEM)	68.7 (0.30)	68.8 (0.50)	0.867 [†]
Number of procedures (n)			
Hip	423	135	-
Knee	643	236	-
Hip : knee (%)	40:60	37:63	0.261
Diabetes (n, %)			
Type I	17 (1.6)	6 (1.6)	0.976
Type II	127 (11.9)	36 (9.7)	0.240
Duration of pre-operative hospital stay (n)			
0 days	990	357	
≥ 1 days	76	17	
0 : ≥ 1 (%)	93:7	95:5	0.075

* likelihood ratio chi-squared test (contingency table), unless otherwise stated

† analysis of variance

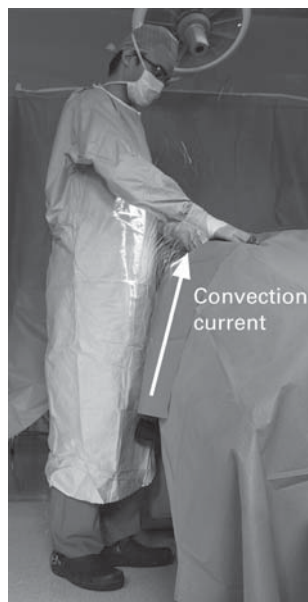


Fig. 6a



Fig. 6b

Time-lapse photographs of bubbles depicting airflow patterns for a lower lumbar spinal implant procedure with a) forced-air warming with the resulting convection current annotated, and b) with conductive fabric warming.

site (Fig. 6). In contrast, conductive fabric did not release sufficient excess heat to establish these convection currents.

Joint infection risks. The demographics of 1437 patients undergoing hip or knee replacement revealed no significant difference between the two types of warming for SSI risk factors of age, type of surgery, diabetes and length of pre-operative stay (Table I). Unfortunately, record keeping was incomplete for the additional risk factors of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection.^{4,18}

The risks of developing deep infection (Table II) were significantly greater for patients undergoing hip *versus* knee replacement (OR 4.1, $p < 0.001$), and patients treated with forced-air *versus* conductive fabric warming (OR 3.8, $p = 0.024$). The factors of age, diabetes and pre-operative length of stay had no significant impact on the risk of infection. Further, the ORs for hip *versus* knee infection were similar for the subgroups of forced-air and conductive fabric warming, having values of 4.1 and 3.5, respectively.

Micro-organisms isolated from septic joints were predominately skin commensals for both forced-air (81%) and conductive fabric (100%) warming (Table III); the remainder were from intestinal bacteria. Of the skin-based organisms, staphylococcus species were the most common sources of infection (93%).

Logistic regression identified a significant reduction in infection rates (Fig. 7) for the conductive fabric (0.8%) *versus* forced-air warming (3.1%) periods ($p = 0.024$, Wald test). Differences in infection rates were significantly different between the conductive fabric and transition periods (0.8% *versus* 3.7%, $p = 0.028$, Wald test); differences were not significant between the forced-air and transition periods (3.1% *versus* 3.7%, $p = 0.662$, Wald test).

Discussion

Forced-air warming was found to have a significant and disruptive impact on the clean airflow patterns over the surgical site compared to conductive fabric warming, which had no noticeable effect. Further, forced-air warming established convection currents that mobilised resident air from non-sterile areas such as the floor and under the anaesthesia/surgery drape into the surgical site. This disruption in the ventilation of the surgical site was associated with significantly higher risks of joint sepsis for the forced-air *versus* the conductive fabric warming groups.

Perhaps the most striking finding was the detection of hot-air convection currents originating where the 'mass flow' of hot air exited from the forced-air warming blanket:

Table II. Univariate comparison of risk factors on the development of deep joint infection (CI, confidence interval)

	Developing infection	Not developing infection	Odds ratio (95% CI)	p-value*
Age group (n, %)				0.818
Youngest third (≤ 64 years)	13 (2.7)	472 (97.3)	1.0	
Middle third (> 64 and < 73 years)	12 (2.5)	459 (97.5)	0.9 (0.4 to 2.1)	
Oldest third (≥ 73 years)	10 (2.1)	471 (97.9)	0.8 (0.3 to 1.8)	
Type of surgery (n, %)				< 0.001
Knee	10 (1.1)	869 (98.9)	1.0	
Hip	25 (4.5)	533 (95.5)	4.1 (1.9 to 8.6)	
Diabetes (n, %)				0.110
None	34 (2.7)	1219 (97.3)	1.0	
Type I or II	1 (0.5)	183 (99.5)	0.2 (0.0 to 1.4)	
Pre-operative stay (n, %)				0.327
0 days	34 (2.5)	1310 (97.5)	1.0	
1 or more days	1 (1.1)	92 (98.9)	0.4 (0.1 to 3.1)	
Patient warming device (n, %)				0.024
Conductive fabric	3 (0.8)	368 (99.2)	1.0	
Knee	1	235		
Hip	2	133		
Forced-air	32 (3.0)	1034 (97.0)	3.8 (1.2 to 12.5)	
Knee	9	634		
Hip	23	400		

* likelihood ratio chi-squared test (logistic regression)

Table III. Bacterial species isolated from septic hip and knees by patient warming device

	Forced-air warming	Conductive fabric warming
Number of operations	1066	371
Number of species identified		
Skin-carried		
<i>Staphylococcus aureus</i>	11	0
<i>Staphylococcus aureus</i> and CNS*	2	0
CNS	12	2
Other	1	1
Total	26	3
Intestinal		
Gram-negative bacteria	6	0
Total	6	0
Total	32	3

* CNS, coagulase-negative staphylococcus

for the hip replacement with upper-body warming convection currents formed near the mannequin's head, whereas for the spinal procedure with lower-body warming, convection currents formed along the lower drape edge by the surgeon's legs. The formation of such convection currents may at first appear to be theoretically unsupported, as forced-air warming exhausts a heated airflow of only 40 cubic feet per minute into a ventilation environment having an airflow of 6000 cubic feet per minute.¹⁹ However, one must consider the effects of surgical lighting, drapes and personnel on ventilation, all of which create localized disturbances of airflow that aid the formation of convection currents.

Prior research in ultra-clean ventilation theatres has shown surgical lighting to be a significant source of

disruption of ventilation through the downstream wake and associated recirculation zone.²⁰ In our study, the use of bubbles allowed us to visualise this recirculation zone, which was found to extend about 1 m below the body of each surgical light. The presence of a raised anaesthesia/surgery drape was shown to further magnify the size and effect of this vortex, as the drape blocked the natural passage of air out of the ventilation field and created a still zone. Lastly, the presence of a surgeon or anaesthetist near this zone created an added obstacle,²⁰ resulting in a situation where even the slightest movement adversely affected the natural airflow patterns over the surgical site. Under such fragile conditions the mass flow of hot forced-air being exhausted from the device was sufficiently buoyant to push upwards and into this locally compromised ventilation region.

The clinical concern regarding the formation of such convection currents is twofold. First, these currents oppose the natural clean airflow patterns that are intended to sweep contaminants down and away from the surgical site.²¹ Thus, contaminants released in the vicinity of the surgical site are less likely to be cleared. Secondly, the upward mobilisation of floor-level and under-drape air could potentially compromise the sterility of the surgical site, as resident air from these locations is typically laden with pathogens shed from the surgical staff.²² Either mechanism offers a plausible explanation for the significant association between the patient warming device and the risks of SSI in this study. Further, the types of organism isolated from septic joints were predominately skin flora and hence likely to have been transmitted by and deposited from the air.²³ It was, however, somewhat unusual that the odds of infection associated with hip replacement were

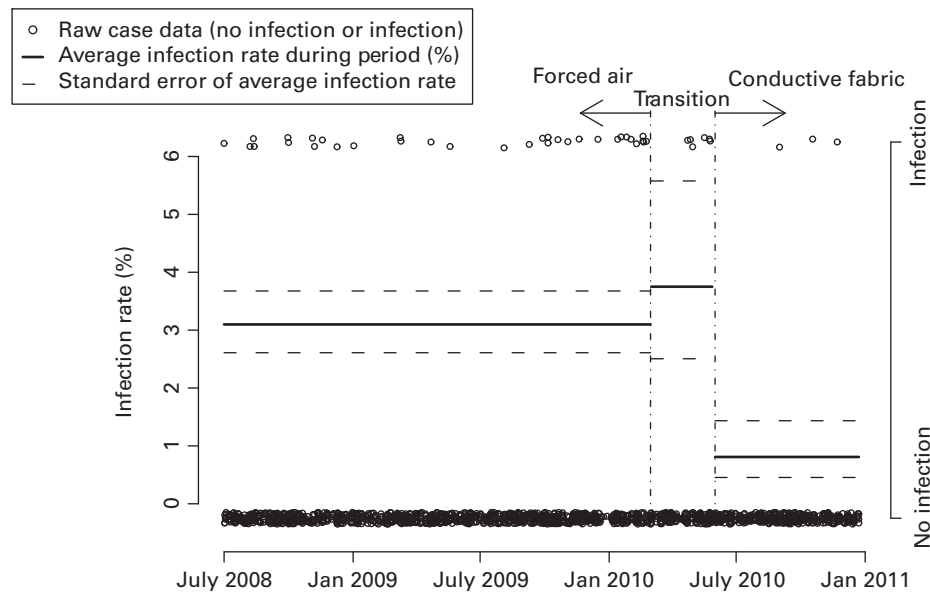


Fig. 7

Graph showing time-based trends of joint sepsis rates for hip and knee replacement cases. The outcome of each individual case is plotted on the right-hand axis (data are jittered to avoid overprinting). The infection rates for each period (forced-air, transition or conductive fabric) are plotted on the left-hand axis. Standard error of the mean was estimated using logistic regression.

4.1 times greater than the odds for knee replacement: typically, infection risks are greater for knee replacement.²⁴ A check of surgical practices revealed no differences in theatre dress or draping techniques between the procedures. Further, the OR for infection was consistent for both the forced-air and the conductive fabric subgroups (3.5 and 4.1, respectively), which suggests that there were no apparent changes in risk factors apart from warming device.


This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010.²⁵ In addition, we were unable to consider all factors that have been associated with SSI, as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection,^{4,18} were not sufficiently detailed in the medical record. Moreover, prior research is limited to a handful of studies that have either looked at the disruption in ventilation due to forced-air warming in conventional operating theatres^{26,27} or evaluated accumulation microbial contamination and emission issues.²⁸⁻³² Research in ultra-clean operating theatres is limited to a single orthopaedic study in which forced-air warming resulted in elevated microbial counts over the surgical site.³³ However, the increase in contamination was deemed to be less than that resulting from the movement of

personnel, and did not exceed recommended bacterial levels. It is not known how these results translate to the range of arthroplasty procedures performed in ultra-clean operating theatres. Even minor differences in factors such as draping, procedural practices and theatre dress are likely to have large effects on both floor-level and under-drape contaminant levels and the formation of convection currents.

National studies on the benefits of ultra-clean laminar-flow ventilation may provide a better indication as to the impact of forced-air warming on the mobilisation of contaminants, as they take into account the full range of surgical draping, procedural practices and theatre dress. Over the past ten years these studies have shown either an upwards trend towards³⁴ or significantly higher^{24,35} infection rates in laminar flow. Yet the results of these studies are not fully conclusive, as they are limited by their clinical design, which omits basic air pollution endpoint measurements such as wound washout or slit sampling. Moreover, the mobilisation of non-sterile air due to forced-air warming may be the explanatory factor, as historical studies^{1,3} on laminar-flow ventilation conducted before the introduction of forced-air warming clearly showed a reduction in the rates of infection. Additionally, the widespread acceptance that forced-air warming reduces the rate of infection has only been demonstrated in colorectal surgery.³⁶

Until the disruptive effects of forced-air warming on ventilation can be fully evaluated with regard to affecting the sterility of the surgical site, the use of air-free patient warming alternatives might be recommended for procedures involving implants carried out in ultra-clean theatres.

Supplementary material

 A video demonstrating forced-air warming is available with the electronic version of this article on our website at www.jbjs.org.uk

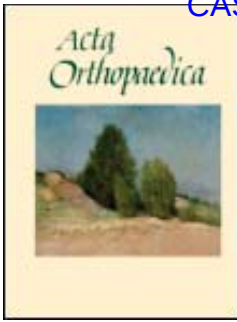
The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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EXHIBIT DX6

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK



Acta Orthopaedica

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Reduced short-term complications and mortality following Enhanced Recovery primary hip and knee arthroplasty: results from 6,000 consecutive procedures

Sameer K Khan, Ajay Malviya, Scott D Muller, Ian Carluke, Paul F Partington, Kevin P Emmerson & Mike R Reed

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Reduced short-term complications and mortality following Enhanced Recovery primary hip and knee arthroplasty: results from 6,000 consecutive procedures

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Background and purpose — Enhanced Recovery (ER) is a well-established multidisciplinary strategy in lower limb arthroplasty and was introduced in our department in May 2008. This retrospective study reviews short-term outcomes in a consecutive unselected series of 3,000 procedures (the “ER” group), and compares them to a numerically comparable cohort that had been operated on previously using a traditional protocol (the “Trad” group).

Methods — Prospectively collected data on surgical endpoints (length of stay (LOS), return to theater (RTT), re-admission, and 30- and 90-day mortality) and medical complications (stroke, gastrointestinal bleeding, myocardial infarction, and pneumonia within 30 days; deep vein thrombosis and pulmonary embolism within 60 days) were compared.

Results — ER included 1,256 THR patients and 1,744 TKR patients (1,369 THRs and 1,631 TKRs in Trad). The median LOS in the ER group was reduced (3 days vs. 6 days; $p = 0.01$). Blood transfusion rate was also reduced (7.6% vs. 23%; $p < 0.001$), as was RTT rate ($p = 0.05$). The 30-day incidence of myocardial infarction declined (0.4% vs. 0.9%; $p = 0.03$) while that of stroke, gastrointestinal bleeding, pneumonia, deep vein thrombosis, and pulmonary embolism was not statistically significantly different. Mortality at 30 days and at 90 days was 0.1% and 0.5%, respectively, as compared to 0.5% and 0.8% using the traditional protocol ($p = 0.03$ and $p = 0.1$, respectively).

Interpretation — This is the largest study of ER arthroplasty, and provides safety data on a consecutive unselected series. The program has achieved a statistically significant reduction in LOS and in cardiac ischemic events for our patients, with a near-significant decrease in return to theater and in mortality rates.

Enhanced Recovery (ER) or fast-track total hip (THA) and total knee arthroplasty (TKA) has become well established (Malviya et al. 2011). This is a multidisciplinary strategy involving patient education, multimodal analgesia, standardized perioperative anesthesia and local anesthetic infiltration, judicious fluid administration, and early mobilization. It has been shown to reduce length of stay (LOS) without increasing re-admission rates (Husted et al. 2008, 2010b, Malviya et al. 2011). Other endpoints reportedly expedited or improved with fast-track programs include functional rehabilitation and patient outcome (Holm et al. 2010, Larsen et al. 2010). Medical complications including thromboembolism are not more frequent using ER techniques (Husted et al. 2010a).

An earlier study showed reduced early mortality in the first 1,500 procedures at our unit under a locally adapted ER programme (Malviya et al. 2011). We wanted to determine whether the beneficial effects of ER arthroplasty would persist in a larger group of patients. We now present the short-term (90-day) outcomes and safety data for the first 3,000 unselected consecutive primary hip and knee arthroplasties performed using this ER program, which we have compared to those from an unselected consecutive series of 3,000 procedures using the traditional (Trad) protocol immediately before the introduction of the ER program. Both protocols are summarized in Table 1.

Methods

The ER program was started in May 2008 and all patients were operated on by 9 consultant surgeons at 2 sites within the same Trust. Only ASA grade-1 and -2 patients were operated on at site 1. Site 2 has a high-dependency facility, and

Table 1. Protocols followed during the different periods in this study. Adapted from Malviya et al. 2011

	Trad	ER
Pharmacological	General anesthesia, spinal or epidural according to anesthetist's preference and patient consent Patient-controlled intravenous analgesia No thrombomodulator	Low-dose spinal anesthesia without any intrathecal opioids with Propofol +/- Ketamine, and Paracetamol +/- Parecoxib Local anesthetic: intraoperative infiltration and postoperative infusion Tranexamic acid
Procedural	Intravenous fluids continuing until next day Perioperative urinary catheterization Mobilization next day	Judicious intraoperative fluid and vasopressor administration Catheterization only if indicated Same-day mobilization
Behavioral	Generic patient and staff education	Patient and staff education on ER principles

patients of all ASA grades underwent procedures at this site.

The pharmacological components of the program included standardized anesthesia and pre- and postoperative analgesia. Analgesia started on the night before surgery with Gabapentin (300 mg). Low-dose spinal anesthesia was administered for each procedure, with sedation or light general anesthesia, and 1 g intravenous Paracetamol with or without 40 mg intravenous Parecoxib. Levobupivacaine (0.125%, 80 mL) was infiltrated intraoperatively in a wide and layered field including joint capsule, muscle, fat, and skin. During wound closure, an epidural catheter complete with microbiological filter was placed within the joint and tunnelled to exit away from the surgical wound. 20 mL Levobupivacaine was infused through the catheter after skin closure, and 3 postoperative boluses were delivered at 6, 14, and 24 h. THA patients received 20-mL boluses and the larger intra-articular space in TKA could accommodate 40-mL boluses (Nechleba et al. 2005). The ambIT pump (Summit Medical Products, Sandy, UT) was used to deliver the boluses in all these cases, and the scrub and ward nursing staff received regular scheduled sessions to train and maintain skills. Postoperative regular analgesia included Gabapentin (300 mg twice daily for 5 days) and Oxycontin (5–20 mg twice daily for 2 days) followed by Tramadol (50–100 mg every 4–6 h). All patients received intravenous Tranexamic acid (15 mg/kg) as a slow bolus at induction.

The procedural measures were introduced with the intention of reducing perioperative blood loss and to facilitate earlier mobilization. Drains were not used. Wound dressings were standardized (Abuzakuk et al. 2006, Clarke et al. 2009). TKAs also received a single-layered crepe bandage and a compressive cuff (AirCast Knee Cryo/Cuff; DJO UK Ltd., Guildford, Surrey, UK). Physiotherapy was started within 3–5 h of surgery. Staff nurses were trained to mobilize patients when physiotherapists were not available. Physiotherapy moved from 5 to 7 days a week as the program started, with each patient being reviewed once immediately after the surgery and twice on each subsequent day until discharge.

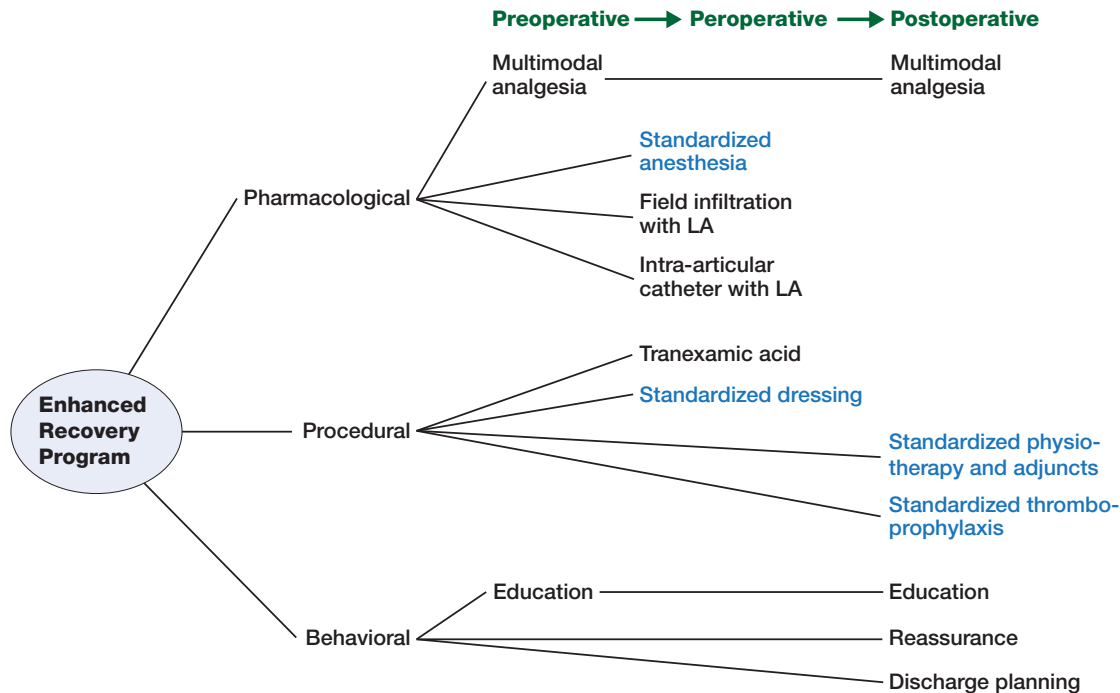
Behavioral changes were fundamental to the program. Patient education started with the initial outpatient consultation, at which mobilization and length-of-stay expectations were discussed and an information DVD was provided.

The message was reiterated by different team members and all patients were invited to attend a patient education class. They were counselled that pain could be expected (Jones et al. 2011). The Figure illustrates the different components in relation to the patients' progression through the ER program.

A uniform blood transfusion policy was adopted in June 2007 (during use of the traditional approach). This is based on national guidelines and has remained unchanged during ER (Department of Health 2007). The transfusion threshold at our unit is a hemoglobin (Hb) value of 80 g/L in the typical physically well patient undergoing arthroplasty. Transfusion is administered routinely at Hb levels less than 70 g/L. For patients with cardiovascular disease, or those expected to have covert cardiovascular disease (e.g. elderly patients or those with peripheral vascular disease), transfusion is considered when the Hb value is less than 90 g/L. Supplementary oral iron is prescribed with or without laxatives if Hb is between 90 and 100 g/L. Orthogeriatric rehabilitation is done on-site, and the LOS data include the rehabilitation stay for the patients who required it. Discharge refers to discharge home. The hospital's discharge criteria did not change with the implementation of the program. These included the patient (1) reasonably pain-free on regular analgesia, (2) voiding urine normally without a catheter, (3) ambulant with 2 crutches at the most, (4) confident alone on the stairs, and (5) able to move the knee 0–90°; with visits organized for district nurses to administer injections of low-molecular-weight heparin.

Certain components of the protocol did change during the implementation of the program. Thromboprophylaxis changed in accordance with evolving guidance from National Institute for Health and Care Excellence (NICE)

The department used aspirin and stockings until October 4, 2006 (midway in the traditional program) when it was changed to Tinzaparin (Innohep; LEO Pharma A/S, Ballerup, Denmark) (4,500 U subcutaneously, once daily). This was continued in the ER program until July 31, 2009. Rivaroxaban (Xarelto; Bayer Schering Pharma AG, Wuppertal, Germany) (10 mg orally, once daily) was used between August 1, 2009 and February 1, 2010, before finally reverting to Tinzaparin (Jensen et al. 2011). Preoperative Dexamethasone was part of the protocol initially but was discontinued because of concerns



This schematic diagram shows the patient's progression through different components of the Enhanced Recovery program.

about potential immunosuppression. Some physical measures targeting *Clostridium difficile* and MRSA infections were introduced over the study period, including chlorine-containing cleaning agents in patient areas (August 2007) and the start of “Deep Clean” (January 2008) and hydrogen peroxide fumigation (June 2008). The antibiotic prophylaxis at the start of the traditional protocol was 3 doses of Cefuroxime (1.5 g, 750 mg, and 750 mg). This was changed in October 2007 to high-dose Gentamicin (4.5 mg/kg), which was continued in the ER program. It was finally changed to Gentamicin (3 mg/kg) and Teicoplanin (400 mg) in February 2009 (Sprowson et al. 2012). The change to Gentamicin led to concerns about renal dysfunction, and the concomitant use of non-steroidal analgesics could not be adopted as a regular feature in our ER program despite their reported benefit in improving postoperative outcomes (Aveline et al. 2009, Schroer et al. 2011). Lastly, there was a national shortage of intravenous Tranexamic acid for 18 weeks (National Electronic Library for Medicines 2010). Instead, the oral preparation was administered in 302 procedures at a dose of 25 mg/kg (maximum 2 g).

Qualified coders collected data on all patient episodes. Data on individual episodes were linked, so that complications resulting in re-admission after a successful discharge were included. By using the appropriate codes (Bramer 1988, NHS Connecting for Health 2009), complication rates after primary joint arthroplasty were identified. We report on surgical endpoints (return to theater (RTT) and re-admission) and medical complications (stroke, gastrointestinal bleeding (GIB), myocardial infarction (MI), and pneumonia within 30 days; deep

vein thrombosis (DVT) and pulmonary embolism (PE) within 60 days; and mortality at 30 and 90 days). No patients were lost to follow-up.

Statistics

The data on LOS were non-parametric, and Mann-Whitney U test was used to analyze differences between the 2 cohorts. Prevalence of comorbidities, surgical outcomes, and incidence of complications were treated as binomial variables. These were calculated as 95% confidence intervals (CIs) and they were also compared using chi-square tests (where p-values of less than 0.05 were considered to be statistically significant).

Results

6,000 unselected consecutive arthroplasty procedures were examined. These included 3,000 traditional procedures (in 2,639 patients) between April 2004 and April 2008 and 3,000 ER procedures (in 2,680 patients) between May 2008 and July 2011. Table 2 compares the demographics and comorbidities between patient episodes in the 2 groups. The ER group had a higher proportion of females, and more patients underwent TKAs than in the Trad group. Also, a higher proportion of ER episodes were coded with hypertension ($p < 0.001$), type 2 diabetes ($p < 0.001$), and chronic obstructive pulmonary disease (COPD) ($p = 0.002$).

The median LOS was reduced by 3 days in the ER group (Table 3). This reduction in hospital stay due to earlier

Table 2. A comparison of demographics and comorbidities between the two cohorts

	Trad	% (CI)	ER	% (CI)	p-value
Demographics					
Mean age (SD)	69 (10)		68 (10)		0.05
Male gender	1,482	49.4 (46.9–51.9)	1,390	46.3 (43.8–48.9)	0.02
No. of TKAs	1,631	54.4 (51.8–56.9)	1,744	58.1 (55.6–60.6)	0.003
Comorbidities					
Hypertension	936	31.2 (28.9–33.6)	1,409	46.9 (44.5–49.5)	< 0.001
Atrial fibrillation	143	4.8 (3.8–6.0)	162	5.4 (4.4–6.7)	0.3
Ischemic heart disease	213	7.1 (5.9–8.5)	249	8.3 (7.0–9.8)	0.09
Diabetes mellitus					
insulin-dependent	21	0.7 (0.4–1.3)	33	1.1 (0.7–1.8)	0.1
non-insulin-dependent	212	7.1 (5.8–8.5)	293	9.7 (8.4–11.4)	< 0.001
Chronic obstructive pulmonary disease	87	2.9 (2.2–3.9)	133	4.4 (3.5–5.6)	0.002
Alzheimer	7	0.2 (0.1–0.7)	9	0.3 (0.1–0.8)	0.8

Table 3. A comparison of surgical endpoints and medical complications in the 2 cohorts

	Trad	% (CI)	ER	% (CI)	p-value
LOS in days, median (range)	6 (1–125)		3 (0–82)		0.01
Blood transfusion ^a	230/1,000	23 (20.5–25.7)	228/3,000	7.6 (6.4–9.1)	< 0.001
Re-admission	141	4.7 (3.8–5.9)	139	4.6 (3.7–5.8)	1.0
RTT (30-day)	60	2.0 (1.4–2.8)	40	1.3 (0.8–2.1)	0.05
Stroke (30-day)	14	0.5 (0.2–0.9)	7	0.2 (0.1–0.7)	0.2
GI bleed (30-day)	18	0.6 (0.3–1.2)	11	0.4 (0.2–0.9)	0.3
MI (30-day)	26	0.9 (0.5–1.5)	12	0.4 (0.2–0.9)	0.03
DVT (60-day)	23	0.8 (0.4–1.4)	14	0.5 (0.2–0.9)	0.2
PE (60-day)	36	1.2 (0.7–1.9)	32	1.1 (0.6–1.7)	0.7
Pneumonia (30-day)	29	0.9 (1.4–2.8)	36	1.2 (0.7–1.9)	0.5
Death (30-day)	16	0.5 (0.2–1.1)	5	0.2 (0.04–0.6)	0.03
Death (90-day)	25	0.8 (0.5–1.5)	14	0.5 (0.2–0.9)	0.1

LOS: length of stay; RTT: return to theater; GI: gastrointestinal; MI: myocardial infarction; DVT: deep vein thrombosis; PE: pulmonary embolism.

^a The transfusion policy changed in June 2007; thus, transfusion data are presented only for the last 1,000 traditional (Trad) arthroplasties, as compared to those for 3,000 ER procedures.

achievement of discharge criteria did not result in a higher re-admission rate. Requirement for blood transfusion was less in the ER group ($p < 0.001$), as was the RTT rate ($p = 0.05$). In the ER group there were statistically significant reductions for 30-day incidence of MI and death. There were 5 deaths within the first 30 days in the ER group, all being in hospital. The causes were perioperative cardiac arrest (day 0), myocardial infarction (day 2), multiple organ failure secondary to pneumonia (day 3), pancreatitis (day 6), and pulmonary embolism (day 8).

Discussion

The results of this study show that adopting an ER program helped achieve substantial reduction in 4 important outcomes. Firstly, the LOS almost halved without an increase in the rates

of re-admission or RTT. Secondly, postoperative blood transfusion requirements were dramatically reduced. Thirdly, the protocol resulted in a fall in recorded 30-day cardiac ischemic events. Finally, and most importantly, both 30- and 90-day mortality declined.

LOS after ER arthroplasty remains a multifactorial issue (Husted et al. 2010a). In our experience, the coupling of procedural innovation and patient education has resulted in a consistent decline in LOS. This has been maintained well beyond the introduction period associated with high staff enthusiasm. The reduced transfusion rate most likely results from the use of Tranexamic acid, confirming its efficacy in reducing perioperative blood loss and allogenic blood transfusion in hip and knee arthroplasty (Alshryda et al. 2011, Sukeik et al. 2011). This was not accompanied by any increase in embolic complications; in fact, the incidence of stroke, DVT, and PE was recorded less often in ER. Despite the higher prevalence of

comorbidities (hypertension, ischemic heart disease, COPD, and type-2 diabetes), ER patients suffered fewer cardiac ischemic events.

The cost of consumables per procedure is modest (e.g. Tranexamic acid €3.67 per gram, Levobupivacaine €28.4, catheter €9.5, ambIT pump €35.5, Cryo/Cuff €47). 7-day rather than 5-day availability of physiotherapy costs €35.5 per procedure. This means an additional unit cost of €112 for THAs and €160 for TKAs. The ER group had 11,400 bed days less than the traditional group. A conservative estimate for the cost of an elective orthopaedic bed was €320 a day in 2008 (Jones 2008). Thus, there was effectively €3.5 million of savings with this cohort of ER patients. These released bed days increased the effectivity of the unit, as evidenced by the shorter period of time to complete 3,000 procedures with the ER program than with the traditional protocol (37 months as opposed to 49 months). Reduced transfusion also has cost implications, at €145–€166 per unit (NHS Blood and Transplant 2012). The reduced medical complications with the associated physical, social, and financial implications further justify an ER protocol.

This study had some limitations. The 2 cohorts were not concurrent. The ER patients and staff looking after them benefitted from educational measures to help reduce LOS. These were both unselected cohorts, and the higher proportions of females and of TKAs during the ER period were incidental. There were changes in DVT prophylaxis regimen during both periods, but these reflected changes in NICE guidance (NICE 2007, 2011). The changes in antibiotic prophylaxis mentioned above may also have had a confounding influence on medical complications. Also, the ER cohort was more recent, and would have intuitively benefitted from advances in diagnostic and therapeutic modalities. Nevertheless, this is the largest series of consecutive and unselected primary hip and knee arthroplasties reported to date, and confirms that Enhanced Recovery is practical, safe for patients, and cost-effective.

SK and MR designed the study. SK and AM collected the data. KE, IC, MR, and PP implemented the protocol. SK, AM, SM, and MR prepared the manuscript. All the authors reviewed the manuscript.

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No competing interests declared.

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EXHIBIT DX7

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MINNESOTA
3

4 In re Bair Hugger Forced Air) MDL No. 15-2666
Warming Products Liability) (JNE/FLN)
5 Litigation,) VOLUME I
) PAGES 1-210
6
7
8
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12

13 VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.
14 LOS ANGELES, CALIFORNIA
15 TUESDAY, JULY 11, 2017
16
17
18
19
20
21
22
23

24 Job No. 124786
25 DORIEN SAITO, CSR 12568, CLR

1 calculation is the simple attributable risk of the
2 exposed which precedes the facts of the substantial
3 contributing cause. That -- you know, that estimate
4 is 74 percent as -- as stated in the sentence on
5 page 17.

6 Q Would an attributable risk of 10 percent be a
7 substantial contributing cause in your opinion?

8 MS. CONLIN: Objection; it calls for
9 speculation.

10 THE WITNESS: I mean, I -- I -- again,
11 10 percent is substantially lower than 74 percent.
12 BY MR. GORDON:

13 Q As an epidemiologist, is there some either
14 absolute number or -- or -- or general range of
15 attributable risk that you would characterize as
16 either substantial or not substantial?

17 A I don't -- I don't have bottom line cutoffs,
18 if that's your question.

19 Q Well, I'm trying to -- my question is, How
20 did you determine that -- that the attributable risk
21 that you found was a substantial contributing cause as
22 opposed to simply a contributing cause?

23 A Well, that was based on this estimate of
24 74 percent of the attributable risk of the exposed.

25 Q And the attributable risk is derived from the

1 relative risk; right?

2 A It's based on the relative risk of the
3 exposed, correct.

4 Q And that's just simply a mathematical --
5 arithmetic computation; right?

6 A As shown here, it was a straightforward
7 calculation.

8 Q But deriving a number for attributable risk
9 when you have a relative risk, that's just a standard
10 arithmetic calculation, RR minus -- divided by --

11 A Correct. That's provided in the sentence
12 before.

13 Q So coming up with an attributable risk,
14 that's not -- that doesn't involved any -- the
15 application of any expertise once you provided
16 relative risk; right? It doesn't involve any
17 judgment, I should say?

18 A Well, it's a standard calculation.

19 Q Okay. So I -- once somebody derives a
20 relative risk and the attributable risk is calculated
21 either by you or somebody else, determining whether
22 the attributable risk is substantial or not, that's --
23 that's just a judgment call for you? Is that --

24 A Well, I --

25 Q -- what you're saying?

1 A I mean, again, here the figure is 74 --
2 74 percent, which is, you know, the majority. So --
3 of the risk of the exposed. So in that case, you
4 know, the word "substantial" seemed applicable.

5 Q You have -- and that's -- we're going to be
6 talking quite a bit today about the McGovern paper,
7 and so let's define that.

8 You -- one of the items upon which your
9 report is based was the -- a paper published in 2011
10 that is listed as Item Number 49 on your materials
11 considered list; is that correct? McGovern, Albrecht,
12 Belani, et al.

13 A That's right.

14 Q "Forced-air warming and ultra-clean
15 ventilation do not mix: An investigation of theatre
16 ventilation, patient warming and joint replacement
17 infection in orthopaedics."

18 A Correct.

19 Q So when I -- when I refer to the McGovern
20 study -- we could -- at some point we could mark it.
21 Probably will.

22 But is -- is that this reference, Number 49,
23 that I'm referring to, sir?

24 A That's fine.

25 Q Okay. And that -- the -- the relative risk

1 of 3.8 from which you derive attributable risk of
2 74 percent, that came out of the McGovern paper;
3 right?

4 A That is correct.

5 Q And you have looked at all of the underlying
6 raw data that had -- hadn't been made available to
7 anyone for that McGovern paper; right?

8 A I did not look at the actual raw data.

9 Q You never looked at it?

10 A I have seen the representations of what is
11 said to be the raw data in discussions of it. But I
12 did not directly examine, count, or compile the raw
13 data.

14 Q I don't understand what you mean.

15 What -- what -- have you seen the -- what
16 you're characterizing as representations of what --
17 How -- how did you phrase that?

18 A I've seen printouts of data sets that are
19 attributed to being perhaps the original data. I
20 believe I saw that in Albrecht's report, perhaps.

21 Q Well, let's go back to your materials
22 considered list. I want to understand something about
23 that.

24 For the list of -- of depositions, the first
25 page of Exhibit C, you list nineteen depositions;

Page 42

1 right?

2 A I'm not --

3 Q They're numbered, I think.

4 A Sorry. Which page is this?

5 Q Page 1 of Exhibit --

6 MS. CONLIN: C.

7 BY MR. GORDON:

8 Q -- C.

9 A Okay.

10 Q So there are -- you list nineteen deposition
11 transcripts and exhibits.

12 A That's correct.

13 Q Now, for some of the transcripts, you -- you
14 identified the -- the deponent, the date, and you say
15 final deposition transcript and Exhibits 1 through
16 blank, whatever they put on those. Like Gary Hansen
17 or Al Van Buren [phonetic], Numbers 5 and 6.

18 Is that right?

19 A That's correct.

20 Q But for several of these, you don't say
21 anything about exhibits. You just say, for example,
22 Example Number 1, Kumar Belani, September 7, 2016,
23 final deposition transcript.

24 A Yes.

25 Q I don't want to assume anything.

Page 43

1 Where you don't list exhibits, does that mean
2 you didn't review the exhibits if there were any or
3 that you just didn't list that?

4 A This is a list of material -- I had materials
5 that were provided by Ciresi Conlin, and -- and this
6 is a straightforward compilation of what was on hand
7 done by my research assistant.

8 Q So your assistant -- this was a review of
9 material by a research assistant?

10 A Sorry.

11 Q In reviewing the material that -- on which
12 you relied for your report, you were assisted by a
13 research assistant?

14 A No. I had a research assistant to organize
15 these materials and try to keep everything organized,
16 if you will.

17 Q Okay. Well, can -- would it be correct to
18 conclude that if there are no exhibits listed for a
19 particular deponent, such as Kumar Belani, that would
20 mean that you didn't review any exhibits, you just
21 reviewed the transcript?

22 A That would be correct.

23 Q Okay.

24 A These are the materials we had.

25 Q And I'm curious because you made reference to

Page 44

1 Albrecht, the exhibit that you described as the
2 printout of a data set. You're listing the two
3 deposition transcripts for Mark Albrecht. It
4 showed -- it doesn't list any exhibits.

5 A Yeah. No. These were provided as -- to me
6 as background in reviewing the reports from
7 Drs. Holford and Borak.

8 Q So prior to rendering your opinion, you
9 hadn't seen --

10 A That's correct.

11 Q -- the data set?

12 A That's correct. It's more recently that saw
13 a thick compilation of the printout.

14 Q Okay.

15 A What was said to be a compilation.

16 Q Okay. Just so we're clear. So when you
17 read -- or -- excuse me.

18 When you rendered your opinion on March 30th,
19 you had not looked at anything that purported to be
20 underlying raw data for the McGovern paper; is that
21 correct?

22 A I had not.

23 Q So -- so if a representation was made to the
24 court that you looked at all the evidence, all the
25 underlying raw data, and concluded that McGovern is an

Page 45

1 absolutely valid study, that would be not be a correct
2 representation --

3 MS. CONLIN: Objection --

4 BY MR. GORDON:

5 Q -- correct?

6 MS. CONLIN: -- as to --

7 THE WITNESS: Again, as I -- as I said,
8 up to the time of March 30, I had not seen raw
9 data from the McGovern study.

10 BY MR. GORDON:

11 Q And you wouldn't have analyzed it, obviously,
12 then to make a determination as of March 30 that the
13 McGovern study was an absolutely valid study; right?

14 A Well, I -- the McGovern study was published
15 in the peer reviewed literature. Again, reanalysis of
16 the raw data is not necessarily a requisite standard
17 for validity.

18 Q And you didn't do any reanalysis; correct?

19 A That's correct.

20 Q Did you make any independent determination
21 that the McGovern paper was a valid study?

22 A I guess I'm not sure what you mean by a
23 "valid study."

24 Q Does the concept of a valid study versus an
25 invalid study have any meaning in the field of

1 epidemiology?

2 A Again, there are many, many aspects of the
3 manuscript that one would look at to decide about what
4 it shows.

5 I just simply don't classify things as a
6 valid study or an invalid study based on -- in the way
7 I think you're using these terms.

8 Q Well, I'm just --

9 Would it be fair to say that you did not
10 independently come to any conclusion regarding the
11 validity of the McGovern study?

12 A Okay. Again, I'm a little puzzled by the
13 word "validity" as you -- as you used it. I have not
14 carefully read what was in the published manuscript
15 and -- and interpreted it.

16 Q Well, I'm just -- I'm just trying to
17 understand. Somebody represented to the court in this
18 case that you, Dr. Samet, had reviewed all the
19 underlying raw data and concluded that McGovern --
20 that McGovern was an absolutely valid study.

21 We've already established that you -- that
22 would be wrong because you didn't look at the
23 underlying data, and that would also be wrong because
24 the concept of being an absolutely valid study doesn't
25 have any -- any significance, it doesn't mean

1 anything; right?

2 A I -- I really don't understand what you're
3 saying. I'm not sure I know what you mean by
4 "absolutely valid."

5 Q It sort of doesn't matter what I'm --

6 Is -- is there any meaning of that phrase
7 that you would use that would allow you to say "Well,
8 yes, I did. I did draw an independent conclusion that
9 it was an absolutely valid study"?

10 A Again, if I -- to use my words, I would look
11 for the study and the conclusion and the methodology
12 as described and the potential for there to be a
13 source and a debate about bias.

14 Q And as of March 30 when you rendered your
15 opinions in this case, you had concluded that there
16 were no sources of bias; is that right?

17 A There were no major sources.

18 Q No major sources of bias.

19 Did you determine there were any minor
20 sources?

21 A Well, I -- I think -- in epidemiology and
22 doing observational studies, there may be sources of
23 bias that are, you know, there but not well-described.
24 But here at least I did not see any major sources of
25 bias.

1 Q And how would you character- --

2 What would you characterize as a major source
3 of bias? I want to use the right phraseology.

4 A Well, I mean, the -- the issues that affect
5 any observational study are threefold. One is
6 confounding, one is problems in measurement, and the
7 third is selection bias.

8 Q And by "measurement," do you mean
9 quantification or tabulation or both?

10 A Error in measurement.

11 Q Would tabulation error be considered a
12 measurement error?

13 A It could be if anything was tabulated.

14 Q And what -- what do you mean by selection
15 bias?

16 A Selection bias is a form of bias that arises
17 from differential participation or dropout from the
18 study in a way that distorts the exposure-outcome
19 relationship.

20 Q And going back to the first potential source
21 of major bias, confounders.

22 You concluded that there were no confounders
23 that would rise to the level of major bias in the
24 McGovern study; right?

25 A That's correct. I concluded that there was

1 no source of confounders that would have led to the
2 estimated level of bias.

3 Q And the only sources of confounding that you
4 mentioned in your report were the prophylactic
5 antibiotic regimen and the thromboprophylaxis regimen;
6 correct?

7 A Correct.

8 Q Did you look at any other potential
9 confounders in the McGovern study besides antibiotics
10 and thromboprophylaxis?

11 A Well, from the information provided -- let --
12 let me step back.

13 A confounder here would have to be something
14 that differed in the two time periods of observation,
15 the Bair Hugger period and the conductive warming
16 period. And that in itself was a risk factor for deep
17 joint infection.

18 So that -- that is a requirement. And from
19 the information available in the publication, there
20 was not an indication of other confounders.

21 Q Based on what was actually in the paper?

22 A Based on what was actually in the paper.

23 And the other comment I would make is, aside
24 from the transition period -- the two-month transition
25 period, any potential temporal confounder would have

Page 50

1 to change rather quickly to introduce bias.

2 Q And in order for you to have determined that
3 something is a confounder -- correct me if I'm wrong.
4 But it's your -- your expert opinion that a particular
5 risk factor has to independently achieve statistical
6 significance. Otherwise, it -- it is disregarded, it
7 doesn't have an impact, it has no results.

8 A It does not necessarily have to achieve
9 statistical significance to be a confounder.

10 Q So something that isn't -- it potentially
11 impacts an outcome, but doesn't do so in a
12 statistically significant way could nevertheless
13 confound a study?

14 A If it met the criteria of being associated
15 with the factor and was also an independent risk
16 factor on its own.

17 Q If bias being -- when you say being
18 associated with it and an independent risk factor on
19 its own, would the association have to be
20 statistically significant in order for it to be
21 considered a --

22 A I'm sorry. Which association?

23 Q Just hypothetically. If you're looking at
24 the question of does X cause Y, and you compared two
25 groups, one that was exposed to X and one that was not

Page 51

1 exposed to X, and the outcome Y.

2 That's pretty standard epidemiological study;
3 right?

4 A Well, it might be a standard data set.
5 That's correct.

6 Q Okay. And -- and if --

7 THE WITNESS: Jan.

8 (The witness handing glass to
9 Ms. Conlin.)

10 BY MR. GORDON:

11 Q -- some of the people in one group that you
12 were comparing to also had an exposure to Z, factor Z,
13 and the people in the group to which you were
14 preparing that group had no exposure to Z, it's
15 possible that Z could be an independent risk factor
16 for outcome Y; right?

17 A Well, that would depend on what is known
18 about Z, and is it, in fact, a predictor of a risk
19 factor for the outcome.

20 Q Okay. Let's -- and that's what I'm
21 talking -- I want to talk about Z. For it to be a
22 risk factor that you would consider a confounder that
23 could give rise to concerns of major bias, does Z have
24 to be --

25 Well, first of all, it would have to be an

Page 52

1 independent risk factor, right --

2 A That's correct.

3 Q -- because Z has an association with Y
4 independent of X; right?

5 A I'm getting a little confused by X, Y, and Z,
6 but yes.

7 Q Okay. Does Z have to be associated with the
8 outcome Y independently but in a statistically
9 significant way in order for it to be considered a
10 potential confounder that would give rise to concerns
11 of substantial bias?

12 A I'm sorry. I think -- if you don't mind,
13 I'll try and say it better.

14 Q Please put it in your words.

15 A That -- that our hypothetical confounder Z --
16 if I understand, your question is, Is it requisite for
17 confounding that it be statistically significantly
18 associated with X? Is that --

19 Q I think the outcome was Y, but that's fine.

20 A Y.

21 Q Whatever --

22 A Y. All right. Probably better to start
23 over.

24 Q You know what, let's -- let's stop the
25 algebra. I apologize that, for getting us off on

Page 53

1 that.

2 One of the issues you looked at was whether
3 use of rivaroxaban as a proper prophylaxis could have
4 been a -- a confounder in your medical opinion;
5 correct?

6 A Yes, that's right.

7 Q Rivarox- -- rivaroxaban was used for part of
8 the Bair Hugger only period but not at all in the
9 HotDog period; right?

10 A Correct.

11 Q So if rivaroxaban was an independent risk --
12 risk factor for the outcome of -- of joint infections,
13 it could be a confounder to any causal determination
14 of -- of the impact of Bair Hugger versus HotDog;
15 right?

16 A I -- in responding, I want to emphasize that
17 you said if it is a risk factor for deep joint
18 infection, which I'm not aware that that is actually
19 established.

20 That is a high -- the requisite requirement
21 for -- for a confounder is it would be an independent
22 risk factor, which is a matter of judgment based on,
23 you know, what is known in general about the potential
24 confounder.

25 Q And -- and -- well, specifically in the case

Page 90

1 is.

2 The issue here was that women in the
3 observational studies who ended up on hormone
4 replacement therapy differed in some ways. Their
5 report for cardiovascular risk was -- who did not.

6 It was not a matter of the general legibility
7 of the nurses, but the difference within the nurses or
8 some other studies at the time between those on HRT
9 who were not assigned randomly but who took it versus
10 those who did not.

11 Q Well, I'm not sure I understand, and that's
12 my problem.

13 The initial observational studies showed a
14 clear benefit from HRT; right?

15 A For cardiovascular disease.

16 Q For cardiovascular, correct.

17 A Right.

18 Q But in subsequent randomized clinical trials,
19 not only was there not that, but there was a
20 detriment -- a statistically significant detriment in
21 cardiovascular disease; right?

22 A There was an increased risk for
23 cardiovascular events, yes.

24 Q Would you agree that there -- there -- that's
25 not an isolated example in the history of medicine

Page 91

1 where -- where an initial approach to some therapeutic
2 intervention was perceived as being either positive
3 or -- or negative based on one or more observational
4 studies that on attempts of replication and/or more
5 focused randomized clinical trials did not prove to be
6 accurate?

7 A I think I said before that not all
8 observational studies with findings that purport to
9 show associations are replicated.

10 Q Wouldn't you agree that a single
11 observational study is without replication generally a
12 weak basis for drawing definitive causal conclusions?

13 A I think a -- the observational study, the
14 findings need to be interpreted in light of what is
15 known about the association with regard to coherent
16 plausibility and -- and so on.

17 Q Well, one of the criteria that suggested that
18 was used by the surgeon general's report and that you
19 yourself discuss is consistency; right?

20 A Yes.

21 Q And that's important because one study may
22 not have gotten it right. But it -- the more studies
23 you have that came -- that come to the same
24 conclusion, the more likely it is that the conclusion
25 is correct and not an outlier result of some bias, a

Page 92

1 result of some unaccounted for confounder, or
2 something like that; right?

3 A Well, having multiple studies with similar
4 findings adds to the confidence in -- in the findings,
5 correct.

6 Q Okay. Well, you go on to say in this 2004
7 report that (reading):

8 "If confounders are recognized
9 and their effects measured, these
10 effects can often be statistically
11 minimized or removed by the
12 analysis of a study. However, if a
13 confounder is poorly measured, or
14 its effects poorly characterized,
15 then its effects cannot be
16 controlled for in the analysis
17 phase of a study, resulting in a
18 causal effect that is distorted or
19 confounded by the unwanted factor.
20 The most extreme version of this
21 phenomenon occurs with unmeasured
22 confounding, causal factors that
23 are not measured at all and whose
24 effects are therefore not
25 controllable, which can result in

Page 93

1 biased estimates and underestimates
2 of uncertainty, because standard
3 analyses implicitly assume an
4 absence of confounding from all
5 unmeasured factors."

6 Did I read that right?

7 A You did.

8 Q And you still agree with that; right?

9 A Yes.

10 Q And the only potential confounders that you
11 even considered for the McGovern study in rendering
12 your opinion were antibiotics and thromboprophylaxis?

13 A Well, again, as I said, with this interrupted
14 time series design -- excuse me -- design, there would
15 have to be other factors that were linked to a time
16 period that fit the definition of confounders. And I
17 just don't have any basis for suggesting what they
18 might be.

19 Q Did you do anything to try and determine if
20 there were potential confounders --

21 A I --

22 Q -- besides the two that you looked at?

23 A Again, these -- my -- my judgments are based
24 on the information and the materials used.

25 Q And you didn't do the analysis where you

Page 94

1 isolated the Bair Hugger period where the antibiotics
2 and the thromboprophylaxis were the same as in the
3 HotDog period.

4 But do you have any reason today to disagree
5 with Professor Holford, Mr. Albrecht, Dr. Reed, and
6 Dr. McGovern that when you compare those two time
7 periods completely eliminating the potential for
8 thromboprophylaxis and antibiotics to be different,
9 there is no difference in the rate of infection?

10 MS. CONLIN: Objection; it assumes facts
11 not in evidence.

12 THE WITNESS: Again, I think I commented
13 on this.

14 One is I'm not sure on an observational
15 basis why these two factors would be kind of
16 considered as independent risk factors.

17 And, second, yes, I have seen the Holford
18 analysis and understand what is there.

19 BY MR. GORDON:

20 Q Let's talk about the antibiotics.

21 Do you recall what the --

22 MS. CONLIN: We're at like 1:15. So.

23 MR. GORDON: Do you want to break now?

24 MS. CONLIN: No, it's up to you. But I
25 know he wants to eat at some point. So I don't

Page 95

1 want you to get into --

2 THE WITNESS: Actually, a break time
3 would be good.

4 MS. CONLIN: Do you mind?

5 MR. GORDON: That's fine.

6 THE VIDEOGRAPHER: The time is 1:15 p.m.
7 We are off the record.

8 (At the hour of 1:15 p.m., a
9 luncheon recess was taken; the
10 deposition resumed at 1:50 p.m.)

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Page 96

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Page 97

1 LOS ANGELES, CALIFORNIA; TUESDAY, JULY 11, 2017

2 1:50 P.M.

3 -0o0-

4 ***

5 JONATHAN SAMET, M.D.,

6 having been previously administered an
7 oath in accordance with CCP 2094, was
8 examined and testified as follows:

9 ***

10 EXAMINATION (Resumed)

11 THE VIDEOGRAPHER: We are back on the
12 record. The time is 1:50 p.m.

13 BY MR. GORDON:

14 Q Dr. Samet, I'd like to talk about
15 antibiotics.

16 There -- do you recall there where two
17 different antibiotic protocols during the McGovern
18 interrupted time series that we were discussing;
19 right?

20 A Correct. Yes.

21 Q Do you remember what they were?

22 A Gentamicin and gentamicin plus teicoplanin.

23 Q Okay. And the HotDog only cohort received
24 the gentamicin-teicoplanin combination for all the --
25 the HotDog cohort period; right?

Page 122

1 infections in the reported surveillance period divided
2 by total number of procedures performed during the
3 period; right?

4 A Correct.

5 Q And in the McGovern paper, what was the rate
6 for the HotDog only period?

7 (Witness reviewing document.)

8 THE WITNESS: I --

9 BY MR. GORDON:

10 Q If it's taking too long, it's on page 5042.

11 A 0.8.

12 Q And that's based on how many --

13 How -- how is that 0.8 derived?

14 A That is 3 over 268.

15 Q Okay. What was the rate for the HotDog only
16 period?

17 A I'm sorry. That's -- that was the HotDog
18 period.

19 Q I'm sorry. I misspoke.

20 What was the rate during the Bair Hugger
21 period?

22 A 3.0.

23 Q 3.0?

24 A That's correct.

25 Q Okay. And what was the -- what were the --

Page 123

1 What was the equation that --

2 A Well, it's 32 over 1,034.

3 Q Okay. And so tell me how -- how the
4 calculation gets to 3.1.

5 A Oh, it's calculated -- it's the odds ratio
6 divided by 2. --

7 Q I -- I misspoke. 3.8; right? The average
8 that you're using is 3.8; right?

9 A Correct.

10 Q Divide that 3 percent -- or 3.0 by 0.8;
11 right?

12 A No. It's the odds ratio from the table.

13 Q Well, how -- how was that -- that 3.8 odds
14 ratio derived?

15 A There's an underlying 2x2 table with warming
16 device, yes/no; infection, yes/no. And then it's
17 calculated as the odds ratio from the table.

18 Q But I'm just trying to understand, What --
19 what are the numbers that are plugged in?

20 A The numbers are the -- sure. The numbers are
21 the 321034 and the 3368.

22 Q Well, is -- is there any relationship between
23 3.0 and 0.8 in terms of coming up with the odds ratio?

24 A The -- are you asking for how an object was
25 calculated?

Page 124

1 Q Yeah.

2 A So it is -- it comes out of the table that
3 describes. And it's simply the cross-product of the
4 diagonals.

5 Q Does it have anything to do with the ratio of
6 3.0 to 0.8?

7 A Well, the same -- the same numbers are -- the
8 same numbers are involved, yes.

9 Q And that if that -- if the -- for example, if
10 the 0.8 number were higher, the odds ratio would go
11 down, wouldn't it?

12 A It would be a different data set, but yes.

13 Q Okay. Well, do you recall when you read
14 Dr. Reed's testimony that he said that there was --
15 that the numbers weren't quite correct, there was
16 actually one more infection in each group?

17 A I'm aware of that discussion, yes.

18 Q Well, were you aware of it before you wrote
19 your report?

20 A I don't think I was.

21 Q Okay. So you're aware of it now?

22 A I'm aware of it now.

23 Q You became aware of it because you read
24 Dr. Holford's report?

25 A I -- probably Holford's report brought my

Page 125

1 attention to it.

2 Q So you hadn't read -- either hadn't read it
3 or just --

4 A I -- you know, again, I -- I remember some
5 discussion about data sets. And I don't know what is
6 the, quote, "correct" -- "correct data set." But I'm
7 aware that Reed commented about the data.

8 Q Okay. If you add one infection to each
9 group, what happens to the odds ratio?

10 A That's -- you know, again, I mean, that's not
11 a question that could be answered generically. I
12 mean, if we calculate it here, I suspect that since 3
13 is a very small number, adding 1 to make it 4 would
14 lower the odds ratio.

15 Q Well, why don't you take a look at
16 Dr. Holford's report here.

17 Is that Exhibit 4?

18 MS. CONLIN: Exhibit 3.

19 BY MR. GORDON:

20 Q 3. And if you'll look at page 3, Footnote 1.
21 (Witness turning to page.)

22 BY MR. GORDON:

23 Q For the moment, I don't want to ask you about
24 Dr. Holford's calculation based on his analysis of the
25 data set and the -- all the other things. He's

Page 126

1 just -- Footnote 1 is just based on Dr. Reed's
2 testimony that was one more infection in each group.

3 Do you have any reason to think that
4 Professor Holford screwed up the calculations that he
5 did there?

6 A Oh, he certainly did the calculations
7 correctly.

8 Q Okay. And assuming those --

9 Well, first of all, do you have any reason to
10 think that Dr. Reed testified inaccurately?

11 A I can't comment on that.

12 Q Okay. Well, if -- if -- if that testimony is
13 accurate and Dr. Holford's calculations are accurate,
14 the odds ratio would be 2.86; right?

15 A According to the calculation shown here, yes.

16 Q And the confidence interval would be 1.03 to
17 8.33; right?

18 A As described here, yes.

19 Q Is that -- would you say that's a strong
20 association or moderately strong association, one that
21 would allow you to feel comfortable in saying there
22 couldn't be any confounders that can account for this
23 odds ratio?

24 A My only comment is 2.86 is lower than 3. --
25 3.8.

Page 128

1 ratio would drop with the addition of one event to the
2 HotDog period when there's very few events there.

3 MR. GORDON: What number are we on? 5.
4 Let me show you what's been marked as Exhibit 5.
5 This was previously part of -- of the McGovern
6 exhibits, which did not have unique exhibit
7 numbers for a multiseries of pages.

8 (The aforementioned document was
9 marked Exhibit 5 for identification
10 by the reporter.)

11 BY MR. GORDON:

12 Q But you did indicate that you had available
13 to you the McGovern testimony and the McGovern
14 exhibits, and there was some discussion -- there was
15 some testimony about this.

16 Do you recall seeing this, Exhibit 5, prior
17 to today?

18 A I think I've seen this.

19 Is this the sixty-day moving average data?

20 Q No. That would be Professor Holford's
21 report. This is --

22 MS. CONLIN: This is Exhibit 21 from the
23 McGovern deposition.

24 THE WITNESS: Okay.

25 ///

Page 127

1 Q And a confidence interval that starts at 1.03
2 is just barely meaningful; right?

3 A I don't think meaningful is determined by the
4 confidence level. Perhaps as significant as 3.05 is,
5 but meaningful, no.

6 Q Okay. But your report was predicated on the
7 assumption that the odds ratio of 3.8 was accurately
8 reported in the McGovern paper; right?

9 A It was based on a report in a peer reviewed
10 paper, correct.

11 Q Okay. And based on the testimony of Dr. Reed
12 at least -- and there are -- and -- and there are
13 other documents that Dr. Holford refers to that
14 corroborate at least his -- his point about there
15 being one more in -- in HotDog -- based on that and
16 the calculations, the -- this -- the odds ratio is at
17 best 2.86; right?

18 A Well, in this -- in this recalculation adding
19 one more event to each group, it's 2.86, correct.

20 Q Does that give you any pause that adding one
21 more infection to each group causes the odds ratio to
22 go from 3.8 to 2.86?

23 A I don't know about giving any pause. But
24 I've commented before that these events are not -- are
25 not so common. So it's not surprising that the odds

Page 129

1 BY MR. GORDON:

2 Q Well, let me see if this helps refresh your
3 recollection. Why don't you -- you know what,
4 Ms. Conlin pointed out to me before we just broke that
5 I had marked an exhibit from Mr. Albrecht's deposition
6 where there was actually writing on it from
7 Mr. Albrecht. So I didn't copy that.

8 MR. GORDON: So this one, I want you to
9 have a copy available to you -- to you. So I'm
10 going to give you Exhibit 6. I will hand you
11 Exhibit 6, which is the same McGovern paper we've
12 been talking about, but it just has no writing on
13 it the way the one in ours did.

14 (The aforementioned document was
15 marked Exhibit 6 for identification
16 by the reporter.)

17 BY MR. GORDON:

18 Q And I would like you on Exhibit 6 to turn to
19 Figure 7, which appears on page 1843.

20 (Witness turning to page.)

21 BY MR. GORDON:

22 Q Does this refresh -- refresh your
23 recollection as to whether you saw Exhibit 5, this
24 version of Figure 7 where the infection rate is
25 reflected as a -- as a moving average as opposed to

EXHIBIT DX8

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

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INTERRUPTED TIME SERIES DESIGNS IN HEALTH TECHNOLOGY ASSESSMENT: LESSONS FROM TWO SYSTEMATIC REVIEWS OF BEHAVIOR CHANGE STRATEGIES

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Abstract

Objectives: In an interrupted time series (ITS) design, data are collected at multiple instances over time before and after an intervention to detect whether the intervention has an effect significantly greater than the underlying secular trend. We critically reviewed the methodological quality of ITS designs using studies included in two systematic reviews (a review of mass media interventions and a review of guideline dissemination and implementation strategies).

Methods: Quality criteria were developed, and data were abstracted from each study. If the primary study analyzed the ITS design inappropriately, we reanalyzed the results by using time series regression.

Results: Twenty mass media studies and thirty-eight guideline studies were included. A total of 66% of ITS studies did not rule out the threat that another event could have occurred at the point of intervention. Thirty-three studies were reanalyzed, of which eight had significant preintervention trends. All of the studies were considered “effective” in the original report, but approximately half of the reanalyzed studies showed no statistically significant differences.

Conclusions: We demonstrated that ITS designs are often analyzed inappropriately, underpowered, and poorly reported in implementation research. We have illustrated a framework for appraising ITS designs, and more widespread adoption of this framework would strengthen reviews that use ITS designs.

Keywords: Professional practice, Cross-sectional studies, Regression analysis, Time factors

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Ramsay et al.

Reliable and valid information on the effectiveness and cost-effectiveness of different interventions is required if policy makers are to make decisions based on these interventions. Rigorous research can help provide such information for policy makers; however, many existing studies are of poor quality (6).

The randomized controlled trial (RCT) is seen as the criterion standard methodology for the evaluation of health care interventions (17). However, there are many interventions for which it is impossible or impractical to use RCTs. For national interventions such as mass media campaigns (35) or within local contexts, the policy makers may wish to assess the impact of specific policies such as the dissemination of clinical guidelines (49). Thus, there is increasing interest in the use of quasi-experimental designs (18).

A common quasi-experimental design used to evaluate such interventions is a before-and-after study design. That is, some measure of compliance or outcome is taken before the intervention and then the same measure is taken after the intervention has occurred. Any changes are then inferred to have occurred because of the intervention. For example, the Working Party of the Royal College of Radiologists undertook a before-and-after study evaluating the impact on general practice of disseminating the Royal College of Radiologists booklet *Making the Best Use of a Department of Radiology* to general practitioners (58). The booklet provided guidelines for radiological investigations and was introduced on January 1, 1990. In the study, the number and type of referrals were measured for the year before and the year after the introduction of the guidelines. There was a reduction in radiological requests after the guidelines were introduced, and it was concluded that the guidelines had changed practice. Several questions remained unanswered. Was the number of referrals already decreasing before the intervention? Did the major National Health Service reforms introduced during 1989–90 impact upon the number of referrals (23;60)? Did the referrals stay at this lower level throughout 1990, or did they begin to return to the original level? These questions demonstrate the potential weaknesses of the before-and-after design (49).

Interrupted time series (ITS) designs can be used to strengthen before-and-after designs (15). In an ITS design, data are collected at multiple instances over time before and after an intervention (interruption) is introduced to detect whether the intervention has an effect significantly greater than the underlying secular trend. There are many examples of the use of this design for the evaluation of health care interventions (16;22;45;67).

An advantage of an ITS design is that it allows for the statistical investigation of potential biases in the estimate of the effect of the intervention. These potential biases include:

- **Secular trend** – the outcome may be increasing or decreasing with time. For example, the observations might be increasing before the intervention; hence, one could have wrongly attributed the observed effect to the intervention if a before-and-after study was performed.
- **Cyclical or seasonal effects** – there may be cyclical patterns in the outcome that occur over time.
- **Duration of the intervention** – the intervention might have an effect for the first three months only after it was introduced; data collected yearly would not have identified this effect.
- **Random fluctuations** – these are short fluctuations with no discernible pattern that can bias intervention effect estimates.
- **Autocorrelation** – this is the extent to which data collected close together in time are correlated with each other. The autocorrelation ranges between -1 and 1 . A negative autocorrelation suggests that outcomes taken close together in time are likely to be dissimilar. For example, a high outcome is followed by a low outcome that is then followed by a high outcome and so on. In contrast, a positive autocorrelation suggests that outcomes measured close together in time are similar to each other. For example, a high outcome is followed by another high outcome. Ignoring autocorrelation can lead to spuriously significant effects (18).

Reviewing interrupted time series designs

To investigate such biases, researchers need to use appropriate statistical methods. For example, time series regression techniques (25) or autoregressive integrated moving average models (ARIMA) (10).

Studies using ITS designs are increasingly being considered for inclusion in systematic reviews (7); however, there has been no published research to assess the methodological quality of ITS studies. We, therefore, undertook a critical review of the methodological quality of ITS studies included in two systematic reviews. The first review evaluated the effectiveness of mass media interventions targeted at improving the utilization of health services (35) and the second review evaluated the effectiveness of different clinical guideline dissemination and implementation strategies (36).

METHODS

Inclusion Criteria

All ITS studies in the mass media review were included. One study from the guideline review was excluded, because it was also in the mass media review (48). Both reviews used the Effective Practice and Organisation of Care (EPOC) Cochrane Group definition of an ITS design (7): (i) there were at least three time points before and after the intervention, irrespective of the statistical analysis used; (ii) the intervention occurred at a clearly defined point in time; (iii) the study measured provider performance or patient outcome objectively.

Data Abstraction

Quality criteria were developed from two sources; from the EPOC data collection checklist (5), and from the classification of threats to validity identified by Campbell and Stanley (15). These quality criteria were agreed by consensus among all the authors in the study and are displayed in Box 1. At least two reviewers independently abstracted the data from each study.

Data Analysis

Descriptive statistics for each review were tabulated. If studies had not performed any statistical analysis or had used inappropriate statistical methods, we reanalyzed the results (where possible). For the purpose of reanalysis, data on individual observations over time were derived from tables of results or graphs presented in the original study. Data from graphs was obtained by scanning the graph as a digital image and reading the corresponding values from the images (35).

Statistical Method for Reanalysis of Primary Studies

Time series regression was used to reanalyze the results from each study. The best fit preintervention and postintervention lines were estimated by using linear regression, and autocorrelation was adjusted for by using the maximum likelihood methods where appropriate (25). First-order autocorrelation was tested for statistically by using the Durbin-Watson statistic, and higher-order autocorrelations were investigated by using the autocorrelation and partial autocorrelation function.

Two effect sizes were estimated (see Figure 1). First, a change in the level of outcome at the first point after the introduction of the intervention was estimated. This strategy was performed by extrapolating the preintervention regression line to the first point postintervention. The difference between this extrapolated point and the postintervention regression estimate for the same point estimated the change in level. Further mathematical details are available from the authors on request. Second, a change in the slopes of the regression lines was estimated (calculated as postintervention minus preintervention slope). We

Ramsay et al.

Box 1. Quality Criteria for ITS Designs	
1. Intervention occurred independently of other changes over time	
DONE	The intervention occurred independently of other changes over time
NOT CLEAR	Not specified (will be treated as NOT DONE if information cannot be obtained from the authors)
NOT DONE	Reported that intervention was not independent of other changes in time
2. Intervention was unlikely to affect data collection	
DONE	Reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention)
NOT CLEAR	Not specified (treated as NOT DONE if information cannot be obtained from the authors)
NOT DONE	Intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported)
3. The primary outcome was assessed blindly or was measured objectively	
DONE	Stated explicitly that primary outcome variables were assessed blindly <i>or</i> outcome variables are objective e.g., length of hospital stay, drug levels assessed by a standardized test
NOT CLEAR	Not specified (treated as NOT DONE if information cannot be obtained from the authors)
NOT DONE	Outcomes were not assessed blindly
4. The primary outcome was reliable or was measured objectively	
DONE	Two or more raters with agreement $\geq 90\%$ or kappa ≥ 0.8 <i>or</i> outcome assessment is objective, e.g., length of hospital stay, drug levels assessed by a standardized test
NOT CLEAR	Reliability not reported for outcome measures obtained by chart extraction or collected by an Individual (will be treated as NOT DONE if information cannot be obtained from the authors)
NOT DONE	Two or more raters with agreement $< 90\%$ or kappa < 0.8
5. The composition of the data set at each time point covered at least 80% of the total number of participants in the study	
DONE	Data set covers 80–100% of total number of participants or episodes of care in the study
NOT CLEAR	Not specified (will be treated as NOT DONE if information cannot be obtained from the authors)
NOT DONE	Data set covers less than 80% of the total number of participants or episodes of care in the study
6. The shape of the intervention effect was prespecified	
DONE	A rational explanation for the shape of intervention effect was given by the author(s)
NOT CLEAR	Not specified
NOT DONE	Any of the conditions above are not met
7. A rationale for the number and spacing of data points was described	
DONE	Rationale for the number of points stated (e.g., monthly data for 12 months postintervention was used because the anticipated effect was expected to decay) <i>or</i> sample size calculation performed
NOT CLEAR	Not specified
NOT DONE	Any of the conditions above are not met
8. The study was analyzed appropriately using time series techniques	
DONE	ARIMA models were used <i>or</i> time series regression models were used to analyze the data and serial correlation was adjusted/tested for
NOT CLEAR	Not specified
NOT DONE	Any of the conditions above are not met
ITS, interrupted time series; ARIMA, autoregressive integrated moving average.	

classified each study intervention as “significant” if either of these effect sizes were statistically significant.

RESULTS

Twenty ITS studies were included from the mass media review (8;9;11;18;24;27;39–42;46–48;51;53;55;61;64;69;71), and thirty-eight ITS studies were included from the guidelines

616 INTL. J. OF TECHNOLOGY ASSESSMENT IN HEALTH CARE 19:4, 2003

Reviewing interrupted time series designs

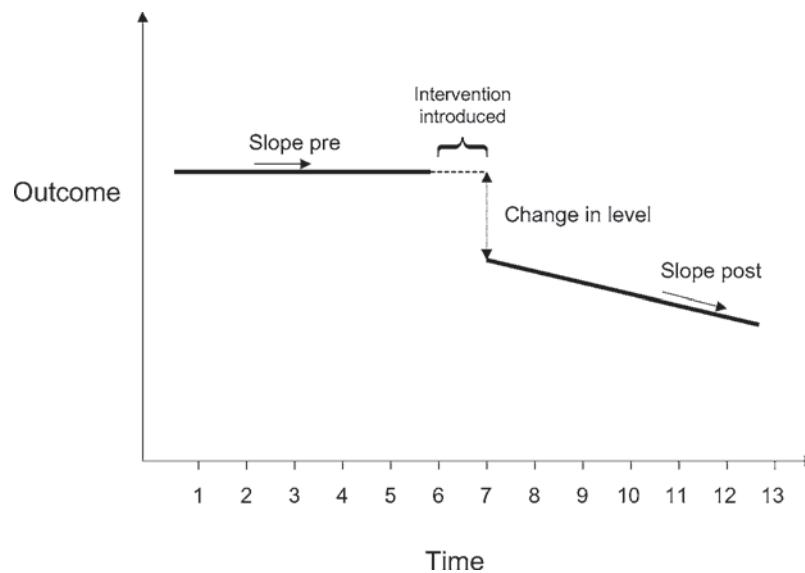


Figure 1. The effect sizes estimated by time series regression analysis of an interrupted time series design.

review (1–4;12–14;16;22;26;28–33;37;38;43–45;50;52;54;56;57;59;62;63;65–68;70; 72–75). Eighteen studies were published before 1990 and forty studies after 1990. The characteristics of the ITS studies are displayed in Table 1. Both reviews had similar numbers of preintervention data points; however, the average ratio of postintervention points to preintervention points indicated that the guideline studies tended to collect more postintervention points than preintervention points within each study. The time interval between data points varied, with “monthly” the most common in both reviews.

The quality criteria for the ITS studies are shown in Table 2. Thirty-eight (66%) studies did not rule out the threat that another event could have occurred at the same time as the intervention. Reporting of factors related to data collection, the primary outcome, and completeness of the data set were generally done in both reviews. No study provided a justification for the number of data points used or a rationale for the shape of the intervention effect.

Table 1. Characteristics of Included Interrupted Time Series Studies

	Mass media review	Guidelines review
Number of included studies	20	38
Median number of preintervention points	9	10
Median number of postintervention points	6	12
Ratio of postintervention points to preintervention points – mean (SD)	0.9 (0.8)	1.9 (2.0)
<i>Time interval between points</i>		
5 days	0	1
1 week	3	3
1 month	9	25
2 months	3	0
3 months	1	5
1 year	4	4

Ramsay et al.

Table 2. Quality Criteria for ITS Studies

Threat to validity	Mass media review (n = 20)	Guidelines review (n = 38)
<i>Intervention independent of other changes</i>		
Done	7	13
Not clear	11	24
Not done	2	1
<i>Intervention unlikely to affect data collection</i>		
Done	19	35
Not clear	1	3
Not done	0	0
<i>Blinded assessment of primary outcome</i>		
Done	17	23
Not clear	3	15
Not done	0	0
<i>Reliable primary outcome measure</i>		
Done	18	24
Not clear	2	14
Not done	0	0
<i>Completeness of data set</i>		
Done	16	37
Not clear	4	0
Not done	0	1
<i>Shape of intervention effect specified</i>		
Done	0	0
Not clear	20	38
Not done	0	0
<i>Rationale for sample size</i>		
Done	0	0
Not clear	0	0
Not done	20	38
<i>Data analyzed appropriately</i>		
Done	5	16
Not clear	0	0
Not done	15	22

Thirty-seven of the ITS studies in the reviews were analyzed inappropriately, of which thirty-three could be reanalyzed. Four “inappropriately analyzed” studies could not be reanalyzed because of the poor quality of the graphs in the primary papers. The results of the reanalyzed studies are shown in Table 3. Eight of the studies had statistically significant preintervention trends (3;11;21;30;52;57;61;75). The mean autocorrelations in the reanalyzed ITS studies were small. All of the interventions in each of the reanalyzed studies were termed “effective” in their original reports, but approximately half of these studies showed no statistically significant differences in slope and level when reanalyzed.

Table 3. Characteristics of Reanalyzed Studies

	Mass media review	Guidelines review
Number of reanalyzed studies	15	18
Significant preintervention trend	3 (20%)	5 (28%)
Autocorrelation coefficient, mean (SD)	−0.18 (0.32)	0.06 (0.40)
Original result significant	15 (100%)	19 (100%)
Original result overturned	7 (47%)	8 (44%)

DISCUSSION

We have demonstrated that ITS designs are being increasingly used to evaluate health care behavior change interventions. Many of these studies had apparent threats to their internal validity that made interpretation of the results unreliable. The design of the studies was often poorly reported and analyzed inappropriately leading to misleading conclusions in the published reports of these studies.

There were no substantial differences between the characteristics of the studies in the two reviews. The mass media studies tended to have smaller postintervention phases. Most of the studies in both reviews had short time series. Short time series suggest that model fitting is performed with less confidence, standard errors are increased, type I error is increased, power is reduced, and hence, failure to detect autocorrelation or secular trends.

Over 65% of the studies were analyzed inappropriately. Most of these studies performed a *t*-test of the preintervention points versus postintervention points. The *t*-test would give incorrect effect sizes if preintervention trends were present and would decrease the standard error if positive autocorrelation were present (19;49). The *t*-test, therefore, should not be used to analyze results from an ITS design.

Many of the studies were underpowered. It is difficult to derive a formula for the sample size (34). As a rule of thumb, if one collects ten pre- and ten post-data points, then the study would have at least 80% power to detect a change in level of five *standard deviations* (of the pre-data) only if the autocorrelation is greater than 0.4 (20). This score is a large effect, and the results from the two reviews suggested that the autocorrelation was around the order of 0.1; therefore, a study with ten pre- and post-data points was likely to be underpowered. In addition, it is beneficial to have a long preintervention phase thereby increasing power to detect secular trends.

This study showed that many ITS studies had analytical shortfalls. In such instances, reviewers may need to consider reanalyzing. The data may be obtained directly from the authors, but if this is not possible, the reviewers can often scan the graphs from the original paper onto a computer as described in the methods section. We recommend reviewers use time series regression techniques for reanalyzing ITS studies. The main advantages of this technique is, first, that it can be performed using most standard statistical packages and, second, that it can estimate the effect sizes more precisely than other time series techniques when the series are short (20;34).

The lack of a randomized control group in an ITS design requires the investigators to be critical of the internal validity of the study. With this in mind, we developed a checklist for reviewers of such designs. This checklist encompassed the major threats to validity of ITS designs as proposed by Campbell and Stanley (15). Generally, the greatest threat to validity is that an event other than the control of the researchers occurred at the same time as the intervention, thereby making causal inferences impossible. It was disappointing, therefore, to note that this threat was not ruled out explicitly in 66% of the studies.

Implications for Researchers

ITS designs may appear superficially simple; however, we have demonstrated that they are often analyzed inappropriately, underpowered, and poorly reported in the implementation research field. To improve the quality of analysis and reporting, we suggest that researchers consider the list of quality criteria described in Box 1.

Implications for Systematic Reviewers

ITS designs are a useful and pragmatic evaluative tool when RCTs are not feasible. It is possible to consider this often neglected study design in systematic reviews and in so doing draw both qualitative and quantitative results on intervention effects. In this study, we have

Ramsay et al.

illustrated the usefulness of a framework for appraising ITS designs, and more widespread adoption of such a framework would strengthen reviews that use ITS designs.

Implications for Policy Makers

Policy makers may find ITS designs a useful way to assess the impact of specific policies that could remain unassessable otherwise. In addition, these designs can often be performed inexpensively from routine data collection.

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EXHIBIT DX9

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

1 MICHAEL R. REED

2 UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

3
4 - - - - -
5 In re Bair Hugger Forced

Air Warming Products

6 Liability Litigation,

7 MDL No. 14-2666 (JNE/FLN)

8 - - - - -
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10
11 VIDEOTAPED DEPOSITION OF

12 MICHAEL R. REED

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14
15
16 London, United Kingdom

17
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23
24 Taken December 4th, 2016

By Rose Kay

25 Job No. 115951

MICHAEL R. REED

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MICHAEL R. REED

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Also Present: Gerlando Scaffidi, videographer

MICHAEL R. REED
I N D E X

MR. MICHAEL R. REED.7

EXAMINATION BY MR. GORDON:7

EXAMINATION BY MR. ASSAAD:154

FURTHER EXAMINATION BY MR. GORDON:219

INDEX OF EXHIBITS
NUMBER DESCRIPTION

[Exhibit 1] Binder of documents18

[Exhibit 2] Binder of documents19

[Exhibit 3] Binder of documents50

[Exhibit 5] Colour flow chart78

[Exhibit 6] Page 1543 of Reed 797

[Exhibit 4] Binder of documents117

[Exhibit 7] CV of Michael Reed157

[Exhibit 8] Document entitled "Forced-air189
warming and ultra-clean ventilation

MICHAEL R. REED

[Exhibit 9] E-mail chain, Bates numbered192
Reed 115

[Exhibit 10] One page of Reed 118195

[Exhibit 11] Article, Bates numbered Reed 84204
through Reed 99

[Exhibit 12] Article titled "Wound205
Complications Following Rivaroxaban
Administration"

[Exhibit 13] Document entitled "RIIO Pilot211
Study"

Page 6

MICHAEL R. REED

Sunday, December 4, 2016

THE VIDEOTAPED DEPOSITION OF MICHAEL R. REED

is taken on this 4th day of December 2016,
at Faegre Baker Daniels, LLP, 7 Pilgrim Street,
London EC4V 6LB, United Kingdom,
commencing at 12:30 p.m.

THE VIDEOGRAPHER: We are on the record in the deposition of
Michael Reed, in the matter of Bair Hugger Forced Air
Warming Products Liability Litigation; in the High Court
of Justice, Queen's Bench Division, job number 15-2666
(JNE/FLN).

The deposition is being held at Faegre Baker
Daniels, 7 Pilgrim Street, London, U.K. on December 4,
2016. The time is half past 12.

My name is Gerlando Scaffidi. I am the legal video
specialist from TSG Reporting, Inc, headquartered at 747
Third Avenue, New York. The court reporter is Rose Kay,
also in association with TSG Reporting.

Would counsel please introduce themselves and the
parties they represent?

MR. GORDON: Corey Gordon, on behalf of the defendants 3M
and Arizant in the U.S. proceedings.

MR. ASSAAD: Gabriel Assaad, on behalf of the plaintiffs.

Page 7

MICHAEL R. REED

MS. ZIMMERMAN: Genevieve Zimmerman, on behalf of the
plaintiffs.

MR. HOLL-ALLEN: Jonathan Holl-Allen, counsel for Mr. Reed.

MS. OKONEDO: Ediri Okonedo, solicitor for Mr. Reed.

THE EXAMINER: Allen Dyer. I am the court appointed
examiner.

Mr. Reed, could you repeat after me?

MR. MICHAEL R. REED.

having been sworn.

testified as follows:

THE EXAMINER: Could we have your full names and your
professional address?

A. Mike -- Michael Richard Reed. I work for Northumbria
Healthcare, which is in Northumberland, U.K.

THE EXAMINER: Thank you. Yes, Mr. Gordon.

EXAMINATION BY MR. GORDON:

Q. Good afternoon, Mr. Reed; and I understand by now that
Mr. is the appropriate title for a senior physician in
the U.K.

A. It's an exam. That's all.

Q. It's really hard, because in the U.S. to call
a physician Mr. would be a real insult; so I am
adapting, but it is a challenge.

You are an orthopaedic surgeon; is that correct?

Page 8

MICHAEL R. REED

A. Yes.

Q. When did you become a consultant orthopaedic surgeon?

A. I think 13 years ago. That sort of order.

Q. Approximately --

A. 2004, I think. 2003, 2004.

Q. And how long was your period of what we would call
residency?

A. Okay. So we do it slightly differently in the U.K., the
residency thing. But we do a junior residency, which is
about four years; and then a senior residency, which is
just in orthopaedics, which is another six years.

I took a year off of my six years, because I did
research, which is sort of recognized by a lot of that.

Q. So you would have left medical school some time in, like
1994?

A. Yes. So we leave medical school at 23. So we don't do
anything generally before medical school over here.

Q. All right. And since you -- well, strike that.

Where did you do your junior residency and your
senior residency?

A. So junior residency, I did in the North East; and then
I did two years of research in Sheffield. And then
I did the rest of the time in the North East on the
senior training program. And then I did a year in New

Page 9

MICHAEL R. REED

Zealand or eight -- no, 15 months in New Zealand, doing
joint replacement essentially in ... and I came back.

Q. What do you mean by the North East, for whose of us who
are not familiar with it?

A. So the North East of England, which is -- we border onto
Scotland, if that helps. So we are just at the very top
of England, on the East Coast.

Q. Is that where Northumbria is now?

A. Yes.

Q. Okay. And is it the Northumbria Hospital Trusts; is
that ...?

A. Yes, so Northumbria Healthcare NHS Foundation Trust.

Q. Explain what the trust is?

A. So the trust is an organization of hospitals which have
the same management structure and the same financial
mechanism, if you like; the same employment structure.

So my hospital, my trust has, I think, a total of 11
or 12 hospitals, of which some will be community
hospitals and some will be more like hospitals with
operating theaters, and some will be trauma hospitals,
or just one now, one trauma hospital out of all of that.

Q. How many of those hospitals do you perform surgery in?

A. Now, three.

Q. Let's start with now. Three?

Page 10

MICHAEL R. REED

A. Yes.

Q. What are they? How are they identified?

A. So one is called the Northumbria Hospital. It is the new one. One is called Hexham General Hospital. And one is called Wansbeck Hospital.

THE EXAMINER: Sorry?

A. Wansbeck.

THE EXAMINER: Wansbeck.

A. Yes.

BY MR. GORDON:

Q. How new is the Northumbria one?

A. It opened in June last year, so that must be almost 18 months.

Q. And prior to that, were you practicing just at Hexham and Wansbeck, or did you replace something with Northumbria?

A. So immediately prior to that, I was operating just in those two. But I have done some operations in North Tyneside Hospital, which is another one of our hospitals in North Shields.

Q. How long have you been affiliated with the Northumbria Trusts?

A. So I have been a consultant the whole time I have been with Northumbria, although I did do some training there

Page 11

MICHAEL R. REED

as well. So I think it's about 2004 since I was appointed, 2003. And I have been at Northumbria since then.

Q. And do you have any additional administrative responsibilities or titles, with respect to overall orthopaedic surgery?

A. So I am head of training currently.

Q. For orthopaedics?

A. For the North East, for orthopaedics; so 67 orthopaedic trainees. So I am currently head of quality for Northumbria, although I am stepping down. My wife is ill, so I am stepping down from that.

What other jobs do I have? I am Chair of the Education Committee for the Orthopaedics Association, British Orthopaedic Association.

Q. Do you currently serve on any NHS committees?

A. Well, I am on the NICE committee, so that's one of our guidelines generators. Well, it is our guidelines generator, if you like.

Q. What does NICE stand for?

A. So the National Institute for Health and Care Excellence. And I am on a committee currently for venous thromboprophylaxis.

THE EXAMINER: You'd better repeat that last word.

Page 12

MICHAEL R. REED

A. Yes, Thromboprophylaxis. So this is stopping clots in the legs, essentially, that go to the lungs.

And I am on the NICE guidance committee for avoiding hypothermia in theater. And I have previously served on them, doing a quality standard for avoiding surgical site infection. And I did the evidence update for NICE on surgical site infection prevention.

BY MR. GORDON:

Q. All right. Let's go backwards.

When did you do that evidence update on avoiding surgical site infections?

A. I would estimate 2013.

Q. And when did you serve on the committee for avoiding -- for providing guidance for avoiding hypothermia?

A. That is currently running, so it runs for maybe a year. You have several meetings, you look at all the evidence; so that's currently in process, if you like.

Q. Is this the first time you have served on that committee?

A. Yes.

Q. Okay.

A. So what happens is they update the guidance every few years. So when they are updating it, there are several meetings and you review lots of evidence and then it

Page 13

MICHAEL R. REED

stops. The guidance comes out, and then maybe in five years time they will do it again and it might be a different committee next time.

Q. Okay. And the venous thromboprophylaxis committee, is it the same thing, about a year?

A. Same thing. And it's, I think, slightly more advanced than the other one, down that road. They are running parallel, but they are not related.

Q. The reason I am asking is: for some reason, I thought you had some responsibilities with NICE, going back several years.

A. So the surgical site infection prevention update was 2013, I think. And the quality standard was about the same time, maybe 2014, something like that; but that sort of order. I don't think I have done anything with NICE before that.

Q. Okay.

I apologize in advance for having thrust in front of you four volumes of material. We have pre-marked them, the volumes 1 through 4 as exhibits 1 through 4.

These are documents that were provided to you a couple of weeks ago, under the High Court's requirements.

MR. ASSAAD: I would like to make an objection at this time,

Page 14

MICHAEL R. REED

just for the record, for the court.

THE EXAMINER: It is not an objection, I don't think. It is something that you want to put on the record.

MR. ASSAAD: Well, I have an objection as well. First of all, I am going to have an objection to globally offering these exhibits as 1 through 4; because as we have realized, within each binder, there's multiple exhibits, multiple different documents and he has not laid any foundation for whether or not they are authentic documents. And to just globally limit it as 1 through 4, it is not commonly done in the United States and I don't think it is done either under English law in trial, to take a whole stock of miscellaneous documents and exhibits and maybe mark it as one big exhibit.

Second, I also object to the use of any of these documents, because we received these documents only a few days before; we received 1,700 pages two days before the date of this deposition, which I think is untimely and goes against the spirit of the sealed order.

THE EXAMINER: Does it not go against the words of the sealed order?

MR. ASSAAD: Well --

MR. GORDON: It does not.

Page 15

MICHAEL R. REED

MR. ASSAAD: It does not go against the words. But, you know, as we have realized, the sealed order was created and written by defense counsel for now --

THE EXAMINER: Okay. You have put your objection on the record.

MR. ASSAAD: I do object. For the purposes of going forward, it is going to be very difficult, unless you identify each document being used and what the exhibit number is for the U.S. court.

It is also improper, unless you want to go through every single page in exhibits 1 through 4. And whether or not he lays the foundation for each document, and whether or not it is authentic, I think each document that's within the binders should be labeled as a different exhibit for ease of use going forward in this deposition, as -- so the court in the United States could rule on the admissibility of each and every document.

MR. GORDON: Counsel, as we have done in the last two depositions, I am identifying, by the specific pagination within each of these group of exhibits, those documents that I am examining the witness on and that is the evidence -- the documents that I am offering.

And if the court finds foundation lacking for any

Page 16

MICHAEL R. REED

particular subset of this, that I specifically enumerate and identify, then so be it. And to the extent that I have adequately identified the specific pages and only those specific pages, that's what we are offering.

These binders correspond to the documents that we have provided to Mr. Reed and to the other deponents, pursuant to the requirements of the London High Court.

So for ease of review and going through the materials in the manner that they were provided to the witnesses and marking them as group exhibits and identifying by specific pagination.

THE EXAMINER: Okay. Have you put on the record -- and this was the question. Have you put on the record an objection to lack of foundation for all of these documents?

MR. ASSAAD: I have a lack of foundation, a lack of --

THE EXAMINER: So you don't have to repeat it.

MR. ASSAAD: But I have one more thing. I just want to say that in accordance with the sealed order, it also refers to the Federal Rules of Evidence and the rules of being at trial. And this is -- we are supposed to conduct this deposition as being a trial before the English courts, as well as the U.S. courts, and this is not how we identify documents by showing 1,700 pages without

Page 17

MICHAEL R. REED

establishing authenticity or foundation.

THE EXAMINER: Okay. Carry on.

MR. HOLL-ALLEN: Sir, may I just say this. For the purposes of the record, the order states --

THE EXAMINER: Hang on. Let me just get my copy. Yes. Paragraph?

MR. HOLL-ALLEN: Subparagraph (f):

"The documents in relation to which Mike Reed is to be questioned by either the defendants or the plaintiffs shall be provided to him in a tabbed and paginated bundle at least 14 days before the date listed in paragraph (b) above."

And I, in the interests of my client, am bound to put on the record this: that a specific inquiry was made by me before the Senior Master as to the likely volume of the material, and the indication was that it would be one or perhaps two Lever Arch files, and I acknowledge that the defendants have not produced anything greater than that in relation to any of the other effective witnesses. But certainly the volume of material that Mr. Reed has been served with is significantly in excess of what we were led to believe.

THE EXAMINER: Well, it grows from time to time. That's one of those things.

Page 18

MICHAEL R. REED

I think the order is perhaps a bit mean, when it provides for him to get them 14 days before and not the other parties, but there we are. That is a matter of hindsight. Gabriel should have been ordered to get them 14 days in advance. I have sympathy for Mr. Reed. There are a number of files.

Anyway, let's get on with the real event.

MR. ASSAAD: Can I have a ruling to identify documents and the foundation, because --

THE EXAMINER: You have put it on the record for the U.S. court. I really think that spending time identifying each document as an exhibit is unnecessary. You have put it on the record. You can say that this was -- you see, we don't have a procedure like this in England. So there's no trial procedure you can follow and rely on in this country. You are restricted to the new -- the federal rules, because we don't do it this way.

MR. ASSAAD: Well, I have a standing order for --

THE EXAMINER: Fair enough. We have a procedure by which all documents are presumed to be authentic unless someone challenges them specifically. And by the time we get to trial, we can have a trial bundle agreed by everyone.

MR. ASSAAD: But each document is labeled as different

Page 19

MICHAEL R. REED

exhibit numbers.

THE EXAMINER: We don't have exhibit numbers.

MR. ASSAAD: Well, whatever number. In the United States, that is the way it is done.

THE EXAMINER: I understand. But you have put your objection on the record for the U.S. court.

MR. ASSAAD: Fair enough.

MR. GORDON: I bet you wish you had gone to law school, huh?

A. I didn't get 14 days either, but we will press on.

BY MR. GORDON:

Q. If you take exhibit 1, which is volume 1. It is in front of you.

(Exhibit Reed 1 marked for identification.)

THE EXAMINER: He needs to have enough space at least to have each file open before him.

BY MR. GORDON:

Q. If you could turn to page 505.

MR. HOLL-ALLEN: Volume 1?

MR. GORDON: Volume 1. Page ...

A. I don't have a 505 in volume 1.

MR. GORDON: The pagination is in the lower right hand corner.

THE EXAMINER: Not on mine. So you'd better tell me which tab number.

Page 20

MICHAEL R. REED

MR. GORDON: They are not paginated?

MR. HOLL-ALLEN: Volume 1 only goes to ...

A. 300 and something.

MR. HOLL-ALLEN: 387.

MR. GORDON: I apologize. Volume 2.

(Exhibit Reed 2 marked for identification.)

THE EXAMINER: I have an unpaginated version.

MR. HOLL-ALLEN: Just for the avoidance of any doubt, there are five files.

THE EXAMINER: Five?

MR. HOLL-ALLEN: Four of them are the -- what we understand to be the defendants' documents, and they are continuously paginated throughout those four files.

THE EXAMINER: Not mine. Not mine.

MR. HOLL-ALLEN: Not yours? I am sorry to hear that. The fifth file is the plaintiffs' documents and those are not -- those are tabbed, but not paginated.

THE EXAMINER: Well, I don't have that either.

MR. GORDON: These are paginated.

THE EXAMINER: It's all right.

MR. GORDON: These are.

THE EXAMINER: I can cope. Just tell me where they are.

MR. GORDON: Where did these come from?

THE EXAMINER: No idea.

Page 21

MICHAEL R. REED

MR. GORDON: Here is 1 and 3.

MR. ASSAAD: These are our 4 to ...

MR. GORDON: Are those paginated?

A. There's numbers on them.

MR. HOLL-ALLEN: These are paginated. It is a complete set, I think.

MR. GORDON: Why don't we switch that out.

(Off the record remarks.)

A. What page are we on, sorry?

MR. GORDON: 505.

THE EXAMINER: 505, yes.

BY MR. GORDON:

Q. And I specifically want to ask you about the document that runs from 505 to 510.

Could you tell us what that -- this particular document is?

A. So this is a paper which looks at the forced air warming machines, if you like, and the potential for them to have bacteria build-up within them; and also to have, sort of, emissions of particles out of the -- out of the hose at the end.

Q. And are you the first listed author in this one?

A. I am, yes.

Q. And when was this published?

MICHAEL R. REED

A. August 2013.

Q. Okay. So with your permission, I am going to refer to this particular study as "Reed 2013".

A. Okay.

Q. Now --

THE EXAMINER: What does it mean, that you are the first named author on this one?

A. So it means various things, actually. So the very traditional route is that the junior author, if you like, goes first.

THE EXAMINER: That is what we have heard to date.

A. Yes. And the senior author would go last. In this particular instance, I went first because I was keen to get this to, if you like, an orthopaedic community, to get the message to the orthopaedic community. So that's the basis of me going first on it.

THE EXAMINER: And what is the AANA Journal?

A. It is a nursing journal, I think. I think it's anesthesia ...

THE EXAMINER: It is in the area of anesthesia and nursing?

A. Yes. That's my recollection.

THE EXAMINER: Okay. Yes.

BY MR. GORDON:

Q. If you could turn to pages 533 through 538.

MICHAEL R. REED

And if you could just briefly identify what this is?

A. So this is a paper which I am a sort of middle author, if you like, and it's a paper that looks at the disturbance of laminar flow with forced air warming during a simulated knee replacement.

Q. And when was this published?

A. This was published in -- actually, I can't read that on the copy. I think 2013.

MR. HOLL-ALLEN: I see --

THE EXAMINER: August 2013, at the top of page 534.

MR. HOLL-ALLEN: Accepted for publication, April 16, 2012, I see at the bottom of 533, copyright 2013.

BY MR. GORDON:

Q. And the first author on this is Belani, sir?

A. Yes.

Q. Again with your permission, I will refer to this study as "Belani 2013"; okay?

A. Okay.

Q. Then I would like you to turn to pages 540 through 547. And again, I will ask you to briefly identify this?

A. Okay, so this is a paper which looks at two things. One is the disturbance of laminar flow using forced air warming in a sort of experimental set-up, and it also has some clinical data. I would like to discuss the

MICHAEL R. REED

clinical data with you actually. I am sure we are going to do that, anyway.

Q. I can assure you, your wish will be granted.

A. Yes, but there is something specific I want to bring to your attention. So when we get there, I will bring that to you.

Q. Okay. When -- strike that.

The first author on this is Paul McGovern?

A. Yes.

Q. And you are the last author?

A. Yes.

Q. And by convention, that makes you the senior author?

A. In this stance, yes.

Q. When was this published?

A. I think 2011.

Q. So I will again, with your permission, refer to this study as "McGovern 2011" and I will probably spend the lion's share of my examination on this study.

So you said you looked at two things; the disturbance and then some clinical data.

Did you do both things essentially simultaneously or around the same time, or was one done first and the other done with some separation of time in between?

A. So my recollection is that the sort of experiment, if

MICHAEL R. REED

you like, the mocked-up experiment was done in the summer of 2010, which would be sort of in the middle, almost in that transition phase of when we were moving between the clinical -- you know, the two different clinical types of warming.

Q. And the clinical part of it was done later; is that correct?

A. No. So it sort of straddles it, I think is how I would describe it. Because my recollection is that, looking at the timings, the theater experiment with the warming, et cetera, was done, I think in May of that year, which would be 2010.

Q. When the McGovern study was initially conceived, did you initially plan on doing the two different components?

A. No, I don't think we did.

Q. What was the one you initially planned to do?

A. Well, you know, the theater-based, lab-based one, if you like, of those two, would be the one that we specifically set out. The other one was more opportunistic.

Q. Okay. And so the one that was, sort of, the progenitor of this study was the airflow disruption component; is that right?

A. Yes.

MICHAEL R. REED

Q. Okay.

How did you come to be interested in that subject?

A. Okay. So I have been trying to recollect the exact order of events; but I am pretty sure I saw a video, which I am sure will be used in some of the evidence, which was smoke coming out of the bottom of a draped theater which was being shown around by Augustine, and I think that was in 2009, perhaps at one of the orthopaedic meetings.

I then heard David Leaper, who I think is another one of your witnesses, speaking at a conference in 2009. And following that, I contacted him by e-mail, actually, and we had an e-mail discussion about his anxiety about the fact that laminar flow was potentially disrupted by forced air.

And then --

THE EXAMINER: Was that the topic of his talk that you heard?

A. I did make some notes on it. I am actually not sure it was. There must have been something in it, in all honesty, because I did e-mail him and the conversation went that way. I have got that e-mail. But there must have been something in his talk that set me off with that discussion.

MICHAEL R. REED

And so -- and he at that point, I think, was a consultant for Augustine.

BY MR. GORDON:

Q. Are you talking about Professor David Leaper?

A. Yes. And in late 2009, we did an experiment in our theater, which was comparing forced air warming with conductive fabric warming, which was the Augustine product.

Q. Also known as the Hot Dog?

A. The Hot Dog. And that involved getting a -- essentially sucking air in, onto culture plates, to see whether there was an increased bacteria load in the theater.

And we did that with a microbiologist. There was a minor celebrity microbiologist who was a bit of a TV personality at that time who came up and did that with us, and they went off and cultured the air, if you like, that sucked onto these plates.

Q. What --

A. So --

Q. What were the results of that?

A. So what that showed was that there was no difference in contamination, whether you use forced air warming or not.

Q. Who financed that study?

MICHAEL R. REED

A. So that was financed by Augustine. He gave our department £5,000 for that.

Q. How did you connect with Dr. Augustine for that financing? In other words, did he come to you, did you go to him? Was there some other ...?

A. Yes, I am not even sure I had met him, but it was through David Leaper. David Leaper essentially arranged that. But I know the money was coming from Augustine. I don't think I had met him at that point.

Q. Okay.

So Professor Leaper arranged for funding from Augustine for you to do a microbiological study?

A. Yes. And David Leaper came as well and we did it on a weekend in theater.

Q. I have to ask. How does a microbiologist become a TV celebrity?

A. So my recollection is, it was something about the sort of -- where bacteria grow and everything. She wasn't a celebrity for that long actually, but she was a slightly colorful character and she was good for TV, I think.

Q. Was this done at one specific hospital?

A. Yes.

Q. Which one?

MICHAEL R. REED

A. Wansbeck.

Q. Okay. Is Wansbeck your primary hospital or was it back then?

A. Yes.

Q. Is it still today?

A. It is much more gray now, but it's where my office is. But I am not sure I operate any more there than I do anywhere else.

Q. Back in that 2009 timeframe, that would have been where you did more surgeries?

A. Yes.

Q. Did -- at that time period in 2009, did Northumbria Hospital Trust have its own microbiology staff?

A. Yes.

Q. Did you involve any of them in this project?

A. No. I think they probably wouldn't have been too keen because, you know, these things involve costs and hassle for the lab techs. So they are not too keen on doing ad hoc experiments like that in the microbiology department.

Q. So the people involved in this were you, Professor Leaper, this -- the celebrity microbiologist; and anyone else?

A. Yes. There would be one or two trainees, of which

MICHAEL R. REED

I can't actually recollect who they were.

Q. Do you recall if Paul McGovern was involved in this project?

A. Yes, I think he probably was. He was actually. He was definitely involved, because subsequently he submitted the abstract.

THE EXAMINER: Because?

A. Because he submitted the paper. So when you do the work, you send it to a meeting and hopefully someone listens.

BY MR. GORDON:

Q. Did you send it to --

A. The Hip Society.

Q. The British Hip Society?

A. Yes.

Q. As a -- for a publication or a presentation or for something else? We have learned that there are different ways of presenting research.

A. Yes, so it would have been for a presentation. So you stand up for ten minutes and you tell everyone about your paper. And I think there's a sort of downgraded category which is a poster, so that's just -- you get to stand next to a laminated sheet about what you did.

Q. So this was submitted to the British Hip Society as

MICHAEL R. REED

a proposed presentation, presumably to a meeting of the British Hip Society?

A. Yes, so 200 or 300 people, probably. Hip surgeons go to that meeting.

Q. And Dr. McGovern was the primary author of this presentation?

A. Yes, I think so.

Q. Was Augustine, as the funder, notified of the results of this -- of your test?

A. So I don't know about officially. I would be surprised if he didn't know. I mean, that paper, it wasn't accepted by the Hip Society, because it didn't -- negative papers unfortunately don't tend to get a lot of air time.

Q. Let's -- I want to make sure that, when the U.S. jury hears this, they understand what you mean by that. What -- in science medical research, what does a negative paper mean?

A. So what we are saying there is that that paper showed there was no difference between the two warming methods. There was no bacterial contamination between the two that we could ascertain; based on what we did.

Q. So -- and what would a positive paper mean?

A. Where one is better than the other.

MICHAEL R. REED

Q. So in your experience, a paper that shows a difference is more likely to be accepted for publication or presentation or posters or something; is that basically what you are saying?

A. I think that's true, yes. Well, that's definitely true. That's well known.

Q. Did you or anyone connected with this research attempt to submit the results of this study to any other forum or journal or anything else?

A. So it may have been submitted to other meetings. I wouldn't necessarily know. Sometimes trainees do submit things; particularly when they have been submitted once, they do submit them to other places. But it wasn't presented, I am pretty sure, anywhere in the end, because it was -- if it was submitted elsewhere, it was rejected.

Q. So would Dr. McGovern have been the person --

A. Yes.

Q. -- doing that? So he is the best person to ask?

A. Exactly.

Q. We will get to do that later this week.

When you actually did this study and found out that there was no difference in bacteria, did that have any impact on how you viewed the issue of disruption of --

MICHAEL R. REED

potential disruption of airflow?

A. So certainly it had an impact, because you have to look at it and say: well, okay, there's no difference. But we had seen, you know, the videos of the -- of air moving from outside of the, you know, essentially the Augustine smoke videos which I am sure you have seen, which show that air is mobilized out -- from the floor, for instance, up into the theater.

So I mean, yes, it's reassuring. And you know, the abstract is pitched as such. But I didn't -- it didn't put it to bed for me, if that's the question.

Q. So after you had done this microbiology study, Dr. Leaper and Dr. McGovern, or Professor Leaper -- or Mr. Leaper, I think. I get the term --

A. He is a Dr. again actually. A bit more confusing, but ...

Q. Okay. If I call you guys "Dr.", please, this is no disrespect. It is just my default position; it is my default salutation of respect.

When the three of you and anyone else -- microbiologists did this study, was there a discussion amongst any of you, after the negative results came out from the British Hip Society that it was not interested in a presentation that: maybe we should look at

1 MICHAEL R. REED
 2 something else, some other aspect of this?
 3 MR. ASSAAD: Objection to form.
 4 THE EXAMINER: You may answer.
 5 A. Well, I think we did go on. With that particular group,
 6 and the microbiologists, we did not take it any further.
 7 But we did go on quite separately, it must have been
 8 seven or eight months later, to do the experiment we
 9 talked about before, in the -- but it wasn't related as
 10 such.
 11 THE EXAMINER: Which experiment was that?
 12 A. That was the one that's in this McGovern et al paper.
 13 That's the one that was in the theater, in the middle of
 14 2010.
 15 THE EXAMINER: Okay.
 16 A. But it was -- yes. I mean, that was then, at that
 17 point, unfunded. I was already asking -- well, I had
 18 asked in 2009 for a randomized trial to be funded by
 19 Augustine, but that wasn't forthcoming.
 20 BY MR. GORDON:
 21 Q. How would you have communicated it to Augustine?
 22 A. Through David Leaper.
 23 Q. What was the reason you were told that Augustine wasn't
 24 going to fund a randomized trial?
 25 A. I think I wasn't particularly told that. I think I was

1 MICHAEL R. REED
 2 told that we would start with the smaller stuff, like
 3 the sort of bacteria one that we just talked about. And
 4 then that was negative.
 5 MR. ASSAAD: I will make an objection to the last question
 6 as hearsay.
 7 THE EXAMINER: You may answer.
 8 A. Sorry, what was the question again; sorry?
 9 BY MR. GORDON:
 10 Q. I forgot too.
 11 A. Okay. We have all forgotten.
 12 Q. I am just trying to understand the sequence. So --
 13 well, let's step back for a second.
 14 What's a randomized trial?
 15 A. Okay. So a randomized trial is when you essentially --
 16 you design the experiments, so things happen at random,
 17 so they are not being driven by anything else. So then
 18 you can decide ultimately what the effect -- what the
 19 effect of that is, and then you can ascribe it to
 20 a particular thing.
 21 So these, in fact, are randomized trials, these
 22 experiments in the operating theaters, because you are
 23 essentially doing things at random and then you are
 24 measuring the effect of that and you will come to the
 25 conclusion that one thing is better than the other.

1 MICHAEL R. REED
 2 But what I was asking Augustine for was a randomized
 3 clinical trial, where you essentially take a patient and
 4 you -- before you do the operation, you assign them at
 5 random to having forced air warming or an alternative,
 6 and then you measure what happens to those patients.
 7 Q. In the hierarchy of research, where does a randomized
 8 clinical trial fall?
 9 A. So a randomized clinical trial falls almost at the top.
 10 So the very best level of evidence is when you get
 11 multiple randomized trials and you see the effect of
 12 them; better analysis of randomized trials. But
 13 a randomized trial, you know, a large well constructed
 14 randomized trial would be a very good level of evidence.
 15 Q. Are they costly?
 16 A. Yes. I would have thought a trial to look at this
 17 particular thing would be probably 1.5, £2 million to
 18 do.
 19 Q. Is that typical for a randomized clinical trial?
 20 A. Of that sort of scale, I mean, you would need lots and
 21 lots of patients. So yes, that would be pretty typical.
 22 It would be cheaper in the U.K. than it would be in the
 23 U.S.
 24 Q. Why would you need -- I will strike that.
 25 Was there something about this, where you would need

1 MICHAEL R. REED
 2 more patients than other kinds of randomized trials, or
 3 just that -- that's the nature of the beast; you need
 4 lots of patients?
 5 A. It is because infection is relatively unusual. You need
 6 to have lots of patients to show the effect of different
 7 intervention. So an infection that occurred in half the
 8 patients, you wouldn't need many patients to show that
 9 one treatment was significantly better than the others.
 10 Q. And when you say "infection" and "usual", are you
 11 speaking specifically in joint arthroplasty?
 12 A. Yes.
 13 Q. Had you ever done any estimate of the number of patients
 14 who would have to be involved, to have a valid
 15 randomized clinical trial that would look at the issue
 16 of the impact of warming modality on joint infections?
 17 MR. ASSAAD: Objection. I am going to object that this is
 18 outside the scope of the subject areas on the list of
 19 the sealed order. Unless he is discussing about the
 20 stuff that he's done in the past in respect to his own
 21 studies, if he has ever done that kind of analysis. But
 22 a reference to a hypothetical and future study, I don't
 23 think that is part of the sealed order about calculating
 24 sample sizes. And if counsel would wish to point to
 25 a certain area, I would be happy to review it, but

1 MICHAEL R. REED
2 I have not seen it in the order.
3 A. Do you want me to answer or ...?
4 MR. ASSAAD: Hold on.
5 A. Hold on.
6 THE EXAMINER: Mr. Gordon?
7 MR. GORDON: Yes?
8 THE EXAMINER: Well, do you accept that objection or do you
9 say it is within the scope?
10 MR. GORDON: No. It's -- we are trying to get his
11 background and his involvement in the development of
12 these studies. And he sought funding from Augustine for
13 a randomized clinical trial. He was denied it.
14 THE EXAMINER: Yes.
15 MR. GORDON: And I am trying to find out what, if any,
16 additional steps he took to gain funding and to --
17 I will let the matter drop.
18 THE EXAMINER: I don't think your question had anything to
19 do with that at all. If you had restricted to that,
20 then I don't suppose there would be an objection. So
21 shall we treat that question as withdrawn and go to --
22 something which goes to: what steps he did take to
23 secure funding?
24 BY MR. GORDON:
25 Q. Sure. When Augustine said "no", was that the end of

1 MICHAEL R. REED
2 your interest in a randomized clinical trial on this
3 issue?
4 A. No. I think -- I don't think we got to specific numbers
5 with Augustine or even a specific cost, but it was like
6 an expression of interest, I would say.
7 So yes, over the years, I have done quite a few
8 trials now, looking at infections at the end point and
9 it depends on what -- as well as how rare the outcome
10 is, like infection, it's also --
11 MR. ASSAAD: Objection. He's answered the same initial
12 question as before. This is going into something that
13 he has done in the past -- the studies that are the
14 subject matter of this case, the subject of his work.
15 MR. GORDON: I am guessing that even in England, it's
16 considered improper to interrupt a witness in the middle
17 of an answer.
18 THE EXAMINER: Well, if this question shouldn't have been
19 asked, then he is entitled to ...
20 The schedule B does seem to be, apart from a few
21 items at the top about useful knowledge of the
22 patient-warming device and factors that influence
23 infection control practices, restricted to specific
24 studies; not studies that weren't done or funded. It's
25 studies that have been produced.

1 MICHAEL R. REED
2 MR. GORDON: It also -- and this was a vigorous point of
3 discussion. It relates to the relationship with funding
4 sources and the fact of Augustine and Augustine
5 companies.
6 THE EXAMINER: Where is that? Unless I am missing a page,
7 which I am not.
8 MR. ASSAAD: Just for the record, I assume that we could all
9 rely on the draft order that's been submitted to the
10 Senior Master, as the current live ...?
11 THE EXAMINER: I assume schedule B has not been touched?
12 MR. HOLL-ALLEN: Schedule B has not been touched. And in
13 fact, the order that was sent to the Master on Friday
14 was made by the Master. So it is not a draft.
15 THE EXAMINER: No, no, no, but we have to rely on the
16 previous version.
17 MR. HOLL-ALLEN: Yes, indeed. So if I can intervene at this
18 point. It is correct that if one turns, for example, to
19 the second page of schedule B, within the scope of this
20 deposition are communications or any potential
21 communications with Dr. Augustine, Augustine Temperature
22 Management and the like.
23 THE EXAMINER: About the studies?
24 MR. HOLL-ALLEN: Well, that was the point that I was moving
25 on to make. Every paragraph is qualified in that way.

1 MICHAEL R. REED
2 THE EXAMINER: Well, I assume that was part of your
3 objections you were taking at the time the order was
4 made, to tie it down to specific published studies.
5 MR. HOLL-ALLEN: And to be fair to the defendants, the way
6 in that respect, in which they were putting it.
7 THE EXAMINER: Okay.
8 MR. HOLL-ALLEN: As I understood it.
9 THE EXAMINER: So Mr. Gordon, can we stick to the studies
10 that were done, rather than the studies that were not
11 done?
12 MR. GORDON: Actually, no. With all due respect, and I can
13 get to the documents where Mr. Reed is pushing the issue
14 of a randomized clinical trial, e-mails back and forth
15 with Dr. Augustine, with Mr. Albrecht, about: the better
16 way to go would be a randomized clinical trial. We will
17 get to those.
18 THE EXAMINER: But that is not within the scope of the
19 schedule B.
20 MR. GORDON: With all due respect, sir, it is, because --
21 THE EXAMINER: Where?
22 MR. GORDON: It relates to the communications, relating to
23 these studies; the ones that were published.
24 THE EXAMINER: Yes. Well, I don't understand how
25 communications about unpublished studies relates to

Page 42

1 MICHAEL R. REED
 2 communications about published studies.
 3 MR. GORDON: The communications about published studies
 4 relate to criticisms of the published studies and the
 5 way to respond to and address those criticisms and why
 6 things were or were not done on a particular --
 7 THE EXAMINER: Let's look at the e-mails.
 8 MR. GORDON: That is what we are --
 9 THE EXAMINER: Let's get to the e-mails. I am not persuaded
 10 at the moment. If you show me relevant e-mails, I may
 11 be persuaded.
 12 MR. GORDON: I will get to it, but you know --
 13 THE EXAMINER: No, I am not going to allow this type of
 14 questioning to continue, unless you lay a basis with
 15 proper e-mail references to this witness. I am simply
 16 not going to allow it to continue.
 17 MR. GORDON: That is fine. I appreciate that Mr. Reed is
 18 kind of cutting to the chase and getting things out,
 19 that I will get to eventually. So I will stick to the
 20 documents. I apologize. This is going to take a little
 21 bit longer this way.
 22 BY MR. GORDON:
 23 Q. Let's go to the McGovern paper, and I want to focus on
 24 the second part of the study, the comparison or the --
 25 what you described as the clinical component.

Page 44

1 MICHAEL R. REED
 2 reply to it and, in fact, it's in your documents; the
 3 e-mail correspondence. And he says he will put it into
 4 the main paper and, in fact, he then says he has put it
 5 in the main paper, but unfortunately it's slightly old
 6 data that is in the main paper. It does not affect the
 7 conclusion in any way, but nevertheless it is not the
 8 latest data they have got in there, and I don't know why
 9 that is.
 10 THE EXAMINER: If Mr. Gordon points you to that specific
 11 section, then you can identify it for us.
 12 A. I will ...
 13 BY MR. GORDON:
 14 Q. I am sure we will get to those details.
 15 Just broadly speaking, the clinical component of it
 16 was a retrospective observation analysis of infection
 17 data; is that correct?
 18 A. So I mean, the data is collected prospectively. So it
 19 is not that we look back. It is collected live. So it
 20 is prospective in that sense, but I would say it is
 21 opportunistic, because we had made the change and then
 22 we looked to see what happened. The data is
 23 prospective.
 24 Q. Was the data being collected -- were the data being
 25 collected for purposes of doing this study?

Page 43

1 MICHAEL R. REED
 2 A. Yes. I would like to speak to you about that.
 3 THE EXAMINER: Well, let's get to it first, where it is; so
 4 that those of us who are not familiar with this document
 5 can identify it.
 6 A. So 540.
 7 THE EXAMINER: Yes, I have got that. Where in the document
 8 are you talking about?
 9 MR. GORDON: I think the discussion begins on page 543 and
 10 it kind of intertwines a little bit, but --
 11 THE EXAMINER: Can I suggest, Mr. Reed, that you allow Mr.
 12 Gordon to ask his questions and answer them and then
 13 before we leave this document, you can make any point
 14 you wish to make about it, unless you think it is
 15 essential for you to lay down your marker before you
 16 answer questions about it.
 17 A. I would prefer to do that, if that is okay.
 18 THE EXAMINER: Fine. Do it that way.
 19 A. So when I was reading this documentation yesterday and
 20 going through e-mails, it's clear to me that some of the
 21 data on the clinical side of the paper is wrong,
 22 slightly wrong. It doesn't affect the conclusion of the
 23 paper and there's still a significant difference. But
 24 there is, in fact, one more infection in each group.
 25 Now, this was e-mailed to Mark Albrecht and he did

Page 45

1 MICHAEL R. REED
 2 A. No. We collect data routinely and we have
 3 a surveillance team, so that is essentially nursing
 4 staff, of which I think we had three at that time, whose
 5 job it is purely to look at infection rates, if you
 6 like.
 7 Q. Okay. So just again, in broadbrush terms. You had and
 8 have a body of infection data and what this study did
 9 was to look back at a particular time period; is that
 10 correct?
 11 A. Well, we collect --
 12 MR. ASSAAD: Objection, misstates the prior testimony.
 13 THE EXAMINER: You may answer.
 14 A. We collect the data as we go, if you like, and we have
 15 done since probably, I think, 2007/2008.
 16 BY MR. GORDON:
 17 Q. What is the reference on page 533 to --
 18 THE EXAMINER: 543?
 19 BY MR. GORDON:
 20 Q. 543, thank you. For demographic information on relevant
 21 risk factors for surgical site infections, SSI,
 22 collected for primary hip and knee replacement
 23 procedures performed at our hospitals -- hospital during
 24 a 2.5-year period starting 1st July, 2008?
 25 MR. ASSAAD: Where are you reading? I am sorry.

Page 46

MICHAEL R. REED

THE EXAMINER: At the top of --

MR. GORDON: At the beginning of the text on page --

MR. ASSAAD: Oh, thank you.

THE EXAMINER: Sorry, what was the question arising out of that?

BY MR. GORDON:

Q. What does that refer to?

A. Well, that's essentially the data that we collect on patients as they come in and have a joint replacement.

Q. Did you just start collecting that data on 1st July, 2008?

A. I think that's probably about right, yes. That's when we went to full-time surveillance. We didn't have a surveillance team. We had part-time surveillance. So in England, there's the -- the NHS law is that you have to submit the one quarter every year, one operation infection rates. And we moved to full-time surveillance in that time. So we had a complete handle on infection rates from that point.

Q. And at the end of that 2.5-year period, did you stop collecting data?

A. No. We still collect data.

Q. The 2.5-year period is the -- would be the time period of the McGovern paper, right? That's -- it's just

Page 47

MICHAEL R. REED

a finding that what -- the book-ends of the study?

A. Yes.

Q. Okay.

So when you -- at the start date of 1st July, 2008, patients were being warmed with the Bair Hugger; is that correct?

A. Yes.

Q. And at some point, you transitioned over from warming patients with the Bair Hugger to warming them with the Hot Dog; is that correct?

A. Yes.

Q. And at some point, you were fully transitioned and only had -- were only using the Hot Dog?

A. Yes.

Q. Is that correct?

A. Yes.

Q. So there were really three periods in that 2.5 years. The first period being Bair Hugger only; the second period being transition; and the third period being Hot Dog; is that correct?

A. Yes.

Q. What was the period of Hot Dog only use?

A. So that's in the paper. It's from -- it was something like June till -- until the end of December.

Page 48

MICHAEL R. REED

Q. Of ...?

THE EXAMINER: Where is this?

A. So this is page 546. And it's the chart which has been written on.

THE EXAMINER: Oh, I see.

BY MR. GORDON:

Q. So June to December 2010?

A. Yes, I think it's June.

MS. ZIMMERMAN: What page was this?

MR. HOLL-ALLEN: 546. This is the table ...

BY MR. GORDON:

Q. Would that be seven months?

A. It feels about right. Six or seven months.

MR. ASSAAD: There's markings on this page. Did you mark ...

THE EXAMINER: I am a bit confused to where the proper lines are, in the light of all these ...

So you used the Bair Hugger from July 2008 to March -- February/March 2010?

A. No. So the -- what's the best way to explain this chart? So if you can try and ignore the scribbles.

THE EXAMINER: Yes, I am trying to.

MR. HOLL-ALLEN: Sir, I am sorry to interrupt. In the plaintiffs' file, there is a clean copy of the same

Page 49

MICHAEL R. REED

document.

THE EXAMINER: Thank you. I don't have the plaintiffs' file.

MR. ASSAAD: And I would prefer to use that, because it seems that this document was used during the Albrecht deposition that was taken in October(?) 2016 and I had to have -- these markings could influence the witness's testimony today. So I would rather have a clean copy.

THE EXAMINER: That is another reason. The principal reason is that it's virtually impossible to understand, with all these markings on it.

MR. HOLL-ALLEN: Would you like to use my copy, sir?

THE EXAMINER: No, it is more important that you have it than I do.

BY MR. GORDON:

Q. Well, let's skip that chart. If you go back to page 543 --

MR. ASSAAD: Are you moving on to the ...

MR. GORDON: No, that was the ...

THE EXAMINER: Which one of these is ...?

A. I think --

BY MR. GORDON:

Q. Under "Joint infection data", there is a reference to: a transition of warming -- forced air warming to

Page 50

1 MICHAEL R. REED
 2 conductive fabric was made in all pre-selected
 3 orthopaedic theaters starting on 1st March, 2010, and
 4 ending on 1st June, 2010.
 5 A. Yes.
 6 Q. So that the transition period would be March, April, May
 7 of 2010; correct?
 8 A. Yes.
 9 Q. So that would be three months?
 10 A. Yes, that looks right.
 11 THE EXAMINER: So prior to March 1st, 2010 it was
 12 Bair Hugger. And after 1st June, it was Hot Dog.
 13 A. Yes.
 14 THE EXAMINER: Thank you.
 15 BY MR. GORDON:
 16 Q. So the Bair Hugger only period was July --
 17 A. July 2008.
 18 Q. July 2008 to the end of February 2010?
 19 A. Yes.
 20 Q. And --
 21 A. Yes.
 22 Q. And after those three months, there was use of both
 23 Hot Dog and Bair Hugger.
 24 A. (Nods.)
 25 Q. Is that right? You have to say "yes" or "no".

Page 51

1 MICHAEL R. REED
 2 A. Oh sorry, yes.
 3 Q. That is all right. And the last seven months of the
 4 period you looked at, it was Hot Dog only; is that
 5 right?
 6 A. So is it seven months or six?
 7 Q. June, July, August, September, October, November,
 8 December.
 9 MR. HOLL-ALLEN: Seven.
 10 A. Seven. There you go.
 11 BY MR. GORDON:
 12 Q. So the Bair Hugger only period was 20 months; is that
 13 right?
 14 A. Well, it was that time, certainly. That feels right.
 15 THE EXAMINER: 20 months.
 16 BY MR. GORDON:
 17 Q. How -- were the data that you looked at collected at
 18 more than one hospital?
 19 A. No.
 20 Q. Which hospital were these data from?
 21 A. Wansbeck Hospital.
 22 Q. Do you recall how you initially gathered the data for
 23 analysis?
 24 A. So the data is gathered by a team of nurses,
 25 surveillance nurses. That's their job. That's what

Page 52

1 MICHAEL R. REED
 2 they do. That's all they do.
 3 Q. I was being a little bit more ministerial in my
 4 question. If you go to the file cabinet and pull it
 5 out, is it computerized data, is it ...?
 6 A. Ah, so I asked them to -- I mean, the way this works is
 7 that we have a report which is produced, of which
 8 there's some in here actually, which is all the various
 9 operations that are done, the risk factors those
 10 patients have and then the outcomes they have; which is
 11 generated by the hospital systems.
 12 But infection is a difficult one. You can't rely on
 13 computers to sort of diagnose that, or you can't rely on
 14 coding. So it's a specific -- you need a specific team.
 15 So they have got that and then they have added their
 16 call on whether there is an infection or not, to that.
 17 Q. Let me ask you to take a look in volume 3, at pages 788
 18 through 1081.
 19 (Exhibit Reed 3 marked for identification.)
 20 MR. ASSAAD: 7 ...?
 21 BY MR. GORDON:
 22 Q. 788 through 1081.
 23 Does that look familiar to you?
 24 A. Yes.
 25 Q. Is that the form of the data on infections that you

Page 53

1 MICHAEL R. REED
 2 would have pulled and provided to your co-authors?
 3 A. Yes.
 4 Q. Who did the actual data analysis?
 5 A. For this paper, Mark Albrecht.
 6 Q. So were these data, pages 788 through 1081, provided by
 7 you to Mr. Albrecht?
 8 MR. ASSAAD: Objection, lack of foundation.
 9 THE EXAMINER: You may answer.
 10 A. I expect so. I don't remember that, but I imagine
 11 I did. There was nothing on here that would -- you
 12 know, there is no data governance issues with this. So
 13 I think, I am almost certain I would have provided it.
 14 THE EXAMINER: Well, it starts on 1st October, 2007,
 15 according to page 788.
 16 A. Yes. I mean, he wouldn't have analyzed that; but this
 17 data goes back, in fact, to 2002.
 18 MR. ASSAAD: I would just like a clarification for my
 19 objection. I am uncertain whether or not this witness
 20 is saying that this is exactly what he gave or used,
 21 or whether he says it looks like it, but he is not
 22 clear. I just want a clarification.
 23 THE EXAMINER: Which is it, Mr. Reed?
 24 A. In all honesty, it looks like it. I don't know if it is
 25 what I gave. But I don't know where he would have got

Page 54

MICHAEL R. REED

1 it, if it wasn't from me.

2 MR. ASSAAD: Do you know whether or not it is accurate?

3 A. I don't know.

4 MR. ASSAAD: All right. Objection, lack of foundation
5 with any questions regarding this -- this spreadsheet,
6 without authenticity or proof that it is accurate -- an
7 accurate picture of the data that Mr. Reed may have
8 used --

9 THE EXAMINER: We have your objection. Yes, Mr. Gordon.

10 MR. GORDON: Now I know why you have those paginated ones.
11 That was my set.

12 THE EXAMINER: No, they came from ...

13 MR. GORDON: The two that I ...

14 THE EXAMINER: You can have it back.

15 (Off the record remarks.)

16 BY MR. GORDON:

17 Q. On exhibit 10 -- actually, strike that.

18 In volume 3, exhibit 3, the data spreadsheet from
19 788 to 1081; under column B, "Site", there are a series
20 of two letters. Do you know what those letters stand
21 for?

22 A. So this is the -- the hospitals that are performing
23 joint replacements. So "HX" would be Hexham. "NT"
24 would be North Tyneside. And WG would be Wansbeck.
25

Page 55

MICHAEL R. REED

1 Q. So these are the data for all three of those hospitals
2 for the time period --

3 A. It looks like that, yes.

4 Q. I think if you turn to page 1082 and 1083, this is
5 a document -- we can tell by the Bates numbers, let's
6 say Augustine 0005490 and 5491. This was sequentially
7 accompanying the spreadsheets that were produced,
8 pursuant to the subpoena to Dr. Augustine, produced by
9 Dr. Augustine.

10 Does pages 1082 through 1083 look familiar to you?

11 MR. ASSAAD: Objection to the -- objection, assumes facts
12 not in evidence. Another objection as to speculation.

13 THE EXAMINER: You can answer.

14 A. Yes. It looks familiar to me.

15 BY MR. GORDON:

16 Q. There is a reference to a Mike Reed database. Do you
17 know what that maybe refers to?

18 A. Well, this is the explanatory table, if you like, for
19 all of those dots and dashes that we have just been
20 looking at.

21 Q. Are you talking about pages 788 through 1081; is that
22 right?

23 A. Yes.

24 Q. So what columns in the large spreadsheet tell us when
25

Page 56

MICHAEL R. REED

1 a given patient has had an infection?

2 MR. ASSAAD: Objection, lack of foundation. I would like to
3 have a standing objection with regards to the
4 foundation. Is that acceptable?

5 THE EXAMINER: Yes.

6 MR. ASSAAD: So this document --

7 THE EXAMINER: You have your objection on the record. It
8 applies to the whole document. I understand.

9 MR. ASSAAD: Well, and every question. I don't want to
10 waive any objections.

11 THE EXAMINER: No. Sorry, repeat the question, Mr. Gordon?
12 Which column is in the ...

13 BY MR. GORDON:

14 Q. In the 788 through 1081 that we looked at, do we find
15 an indication that there has been an infection?

16 A. So as I said before, there's -- this database is looking
17 at the -- where it was done, the complications and the
18 co-morbidities.

19 This database is then given to the surgical site
20 infection surveillance team and then they populate it
21 with a field at the end. This is what they have done in
22 this -- certainly some of these cases.

23 So it is an additional field. Like I said, it is
24 not collected by computer. It is done by an actual
25

Page 57

MICHAEL R. REED

1 surveillance team whose job it is just to do that. So
2 it is not from hospital episode statistics, which is
3 where this has come from.

4 THE EXAMINER: This is a record of all hip and knee
5 operations, is it?

6 A. Yes, yes.

7 THE EXAMINER: Where do we find an identification of which
8 ones resulted in an infection; which column?

9 A. I am not sure it is on this. It might be on this.

10 MR. GORDON: On the --

11 A. There are some. If you look at page 1051, it's --
12 unfortunately it is not very helpful, because it's
13 printed out across many, many pages.

14 THE EXAMINER: Yes, I understand that.

15 A. But if you see in cell 4602 --

16 THE EXAMINER: 1051.

17 A. There is one identified there and the bugs are next to
18 it.

19 MR. GORDON: So since this is an Excel spreadsheet, it is --
20 rather than having it over half the length of the table,
21 it is printed on multiple pages. But if we look back
22 for the identifier 4602 --

23 THE EXAMINER: If you look back at what?

24 BY MR. GORDON:
25

Page 58

MICHAEL R. REED

Q. On page 1047, 4602, that coding would indicate that this was something that was done at Wansbeck General; is that right?

MR. ASSAAD: Objection, leading.

A. Sorry, what page are you on; sorry?

MR. GORDON: 1047.

A. What was the cell number?

BY MR. GORDON:

Q. Let's track 460 to -- all the way through; and I won't ask a leading question.

What hospital was 4602 performed at?

A. Well, it's a little tricky to tell, given they are all -- running from the sheets. But 4602? I can't really see it, with the quality of this print.

Q. On 1047 you can't, under column B?

A. Yes. On 4602, I can't identify it. 4602. Yes, I think I can read it here. It was Wansbeck General. Patient aged 76. Is that right?

Q. And what type of procedure was it?

A. A hip replacement.

Q. What was the date of the surgery?

A. The --

THE EXAMINER: Is yours a very poor copy? Because mine is quite clear.

Page 59

MICHAEL R. REED

A. I am struggling to focus, unfortunately, with the light in my eyes. It is very small. I probably need to wear glasses. 15 September, 2010, I would say.

BY MR. GORDON:

Q. And when -- if we go back to the page that I pointed out, 1051, under 4602, under the column "BF", what does that tell us?

A. What page are you on now?

Q. 1051.

A. On 4602, it says: "infection Staph Epidermis".

Q. Is there a date indicated there?

A. Yes. It looks like -- sorry, I can't really focus.

THE EXAMINER: 3rd October.

A. 3rd October, 2010.

BY MR. GORDON:

Q. And what does that date refer to?

A. I suspect -- I don't know. Probably the diagnosis date.

Q. What was the -- in the McGovern study, what was the time period of surveillance that you included? In other words, how long after the surgery was an infection one that got counted in your study?

A. 60 days.

Q. So if the surgery -- if 4602 was performed on 15th September, 2010 and diagnosed on 3rd October, 2010,

Page 60

MICHAEL R. REED

would that have been included or excluded in your count?

A. When was the surgery done, sorry?

Q. It was done on 15th September, 2010.

A. It would be included.

Q. Okay. And what is staph epidermis?

MR. HOLL-ALLEN: Epidermis.

A. So yes, it is a bacteria. It is a fairly common sort of infection in a joint replacement.

BY MR. GORDON:

Q. How was that column, the "BG" column populated? Is it before or after this has been reviewed by the surveillance team?

A. Well, they populate it.

Q. Okay.

A. They populate it.

Q. So if there's a "yes" and a date and a bacteria indicated, does that indicate that that has already been identified and confirmed by the surveillance process?

A. Yes. I mean, that's -- they have written it. The only caveat, I would say, is that some people will be ultimately removed if they are hip replacements for trauma. That is the only caveat, I would say, but ...

THE EXAMINER: If there is ...?

A. If it is a hip replacement that has been done for

Page 61

MICHAEL R. REED

trauma. So if they have fallen and broken their hip, then they fall in a different classification system because they are much higher risk. So generally they have got their own surveillance. We do still measure them, but they don't fall into planned joint replacement territory.

BY MR. GORDON:

Q. It appears at 1060, there is a category under "AZ" that describes the -- whether it is trauma or non-trauma?

MR. ASSAAD: What page?

MR. GORDON: 1060.

MR. ASSAAD: 1060.

A. I am not sure that would be a reliable way of saying whether it was trauma or not. It seems to me, that's the way the hospital is paid. And it's -- I think, do you have DRGs in the States? But it's essentially -- it's the way they are paid. I wouldn't necessarily rely on saying that's trauma or not.

THE EXAMINER: Well, every one on the page, I think, apart from one, refers to a non-trauma category. Is that a fairly accurate indication?

A. I mean, it might be. But I think there are sometimes operations that fall into different groups, because that's a very wide group.

Page 62

MICHAEL R. REED

THE EXAMINER: Okay.

A. I mean, there is an enormous amount of operations that fall into those groups. You are probably right, but I don't -- I think a coder wouldn't rely on that to say whether it was trauma or not.

BY MR. GORDON:

Q. When you initially saw a printout of data for use in the McGovern study, did you limit it to non-trauma, hip and knee surgeries?

MR. ASSAAD: Objection, misstates the prior testimony. Lack of foundation. He never stated he saw a printout.

THE EXAMINER: You can answer.

A. So normally, the patients you get on here are elective. So there will be some that come on, that are not elective, and then they will be removed by the surveillance team and put -- not actually removed, but put into a different category of joint replacement.

BY MR. GORDON:

Q. When you compiled the data for the McGovern study, did you in any way try to separate the trauma and the non-trauma patients?

MR. ASSAAD: Objection, misstates the prior testimony.

THE EXAMINER: You may answer.

A. I mean, we definitely attempted to do that, because this

Page 63

MICHAEL R. REED

database is meant to be just planned cases, just elective cases.

BY MR. GORDON:

Q. Okay. And by --

A. But we do know that other ones get in through coding and then they will be taken out in the sort of data cleaning process.

Q. By this database, you mean the 788 through 1050 -- 1081?

A. So you know, before we would publish, if you like, on infection rates, then we would go through it, we would check every case is as -- you know, every case, whether the infection is trauma or not. You might by chance end up pulling one out, you might not. I am not aware whether we did with this study.

Q. Okay. The data here, on 788 through 1081, as Mr. Dyer pointed out, began on 1st October, 2007. What was your reasoning for commencing the Bair Hugger only period on 1st July, 2008?

A. So my recollection is that we got a full-time surveillance team at that point. So as I said, previously in the U.K. you only have to do a quarter. Actually, you can choose which operation you do. So you might not have full-time surveillance prior to that.

THE EXAMINER: So one operation, one quartile, per annum?

Page 64

MICHAEL R. REED

A. Correct. That's the national standard. But we have moved to doing every operation full-time; and that's why we have got that reliable data. So there would be big gaps in the period. If you looked at 2006, you might only have a quarter of the year populated, which would be very unreliable data.

THE EXAMINER: Yes.

BY MR. GORDON:

Q. So I really want to drill down on the timing; and that is critical. I am going to ask you to take a look at volume 2, pages 487 through 490.

A. Okay.

Q. Have you seen this before?

A. I saw it yesterday.

Q. Is that the first time you saw it?

A. I'm not sure.

MR. ASSAAD: I am going to object for lack of foundation for any questions being asked, if he hasn't established foundation. He has written this document -- the authorship of this document --

THE EXAMINER: You have made your objection. Keep objections short.

MR. ASSAAD: Well, I need to put all the objections for the U.S. court.

Page 65

MICHAEL R. REED

THE EXAMINER: I know.

MR. GORDON: They are all preserved.

THE EXAMINER: I am familiar with how U.S. attorneys --

MR. ASSAAD: They are --

MR. GORDON: The only objection is: waives form or foundation.

MR. ASSAAD: I am only doing it for trial --

BY MR. GORDON:

Q. Do you know who Julie Gillson is?

A. Yes. Julie Gillson was one of our matrons.

Q. What is a matron?

A. So it is a senior nurse, essentially.

Q. Was she one of the SSI surveillance nurses?

A. No. So Julie is a matron, so the senior nurse within surgery, if you like. Gail Lowdon leads the surgical site infection surveillance team.

Q. And if you look at the front page of this document. At page 71, the very last paragraph, it says during --

THE EXAMINER: Where are you?

BY MR. GORDON:

Q. Page 71. Oh, I am sorry.

THE EXAMINER: 487.

MR. GORDON: 487, thank you. Page 487, the last full paragraph on the page:

MICHAEL R. REED

"During the last two quarters of 2008/2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in the THR/TKR and repair neck of femur between 3.5 percent and 5.7 percent and was regularly receiving letters from the HPA informing the trust of its high outlier status for SSI."

First of all, did I read that correctly?

A. Yes.

MR. ASSAAD: Objection. Move to strike for hearsay.

BY MR. GORDON:

Q. Did --

THE EXAMINER: (Overspeaking.) ... moving on to a question --

MR. ASSAAD: He can't read evidence in, without establishing a foundation. I am saying this is hearsay. He is reading someone else's words into the record. He is basically advocating this point. Objection for hearsay.

BY MR. GORDON:

Q. Do you recall there being a period of time when the Northumbria Healthcare Trust was getting letters from the HPA about SSI rates?

A. Yes.

Q. And what were those -- first of all, what is the HPA?

MICHAEL R. REED

A. So the HPA is the Health Protection Agency and they are the group that collate the national database, based on people collecting it locally. So Gail Lowdon who leads our surgical site infection surveillance team, a member of her team will be uploading that information nationally, if you like, to the Health Protection Agency.

The issue with that is that not every trust puts in the data as we have established; and the infection rates that they quote are very low and, in fact, they have -- I mean, the government advisers on infection have publicly written to say that their quotes -- they quote very low infection rates, unrealistically low, because the surveillance system is poor in many trusts?

THE EXAMINER: Do you have a recollection of these letters being received?

A. Yes.

THE EXAMINER: Okay.

BY MR. GORDON:

Q. And what did Northumbria do in response to those letters?

A. So I mean, we have done lots of things, as I think has become clear. We have made loads of changes over a period, a sustained period, to try and reduce the

MICHAEL R. REED

infection rates.

Q. Was there any type of a committee or a working group formed?

A. Yes. So there was a surgical site infection prevention committee, which I chair.

Q. And when was that formed?

A. It may actually even be on here. About 2008, maybe even 2007. That sort of timescale.

Q. And that's your independent recollection?

A. Yes.

Q. So the reason I say that is that on page 548, it says that the multiple -- a multi-disciplinary team formed the trust SSI group and the first meeting took place in December 2008.

A. There you go then.

Q. Well, if you --

THE EXAMINER: What is the --

BY MR. GORDON:

Q. If your recollection is different than what is here --

A. Yes, I think that feels right and she would know. What I would say is that we may have been doing stuff before that, before we did a formal meeting, but it would not have been long before that.

Q. And there is a reference in the next paragraph to:

MICHAEL R. REED

"The first action point of this meeting was to place a successful bid to appoint two full-time SSI nurses on a 12-month secondment."

MR. ASSAAD: Objection, hearsay.

BY MR. GORDON:

Q. And my question is: was there -- were there full-time SSI nurses prior to whenever this multi-disciplinary group first met?

A. Yes, so the -- the surveillance was done -- I mean, we should probably go back one step.

So we were named in the paper, based on the 2007 data, as having a high infection rate. And after that, we went to full-time surveillance, some time probably in early 2008, but we didn't have the business case and people -- and people formally appointed to those rules. They were being done, I think, by infection control, rather than by a surveillance team. Same methodology.

MR. ASSAAD: I am going to object again to those line of questions. It is not part of the subject matter of the sealed order. It has nothing to do with the studies that he has been performing, that it has been limited to -- by the Senior Master.

THE EXAMINER: He is still in the --

MR. ASSAAD: I mean, we -- well, it really isn't. It is

Page 70

1 MICHAEL R. REED
2 dealing with what these two people wrote, regarding
3 infection control that they set up a committee to do
4 a bunch of stuff, that has nothing to do with the
5 McGovern study, the Belani study or any of the other
6 studies.
7 THE EXAMINER: Well, at the moment, it seems to me that it
8 relates to the McGovern study.
9 MR. ASSAAD: How does it relate --
10 MR. GORDON: It relates exclusively to the McGovern study
11 and it is the category of the infection control
12 procedures.
13 MR. ASSAAD: Procedures, but not how they set it up, who is
14 on the committee, what the history is --
15 MR. GORDON: Well, your objection is noted, Gabriel. Let's
16 start this game playing.
17 THE EXAMINER: Let's proceed.
18 MR. ASSAAD: Stop what?
19 MR. GORDON: Game playing.
20 MR. ASSAAD: Okay. Don't accuse me of playing games, sir.
21 THE EXAMINER: Let's get on with the questions.
22 BY MR. GORDON:
23 Q. Mr. Reed, if you turn on to page 421 of the same ...
24 THE EXAMINER: Where are we?
25 BY MR. GORDON:

Page 71

1 MICHAEL R. REED
2 Q. 421. Can you identify the people in that?
3 A. So the lady in red is a nurse and the lady in black is
4 the surgical site infection coordinator, if you like.
5 I am in that photo. And the other guy is -- I couldn't
6 tell you his name, but he was from one of the companies.
7 Q. Do you know what he is holding?
8 A. Yes. Some -- it is like an award for reducing infection
9 rates.
10 Q. And the award from whom to who?
11 THE EXAMINER: I must say, I do not think this is assisting
12 our progress very much, studying this photograph.
13 MR. GORDON: No, I agree.
14 THE EXAMINER: Let's get back to the paper.
15 MR. GORDON: Again, I keep getting diverted. I want to get
16 the timeline of the infection control changes. That is
17 the sole interest I have --
18 THE EXAMINER: How does looking at this photograph advance
19 that?
20 MR. GORDON: We are going to get foundation objections up
21 the wazoo about everything else, all -- piece by piece.
22 BY MR. GORDON:
23 Q. Mr. Reed, in this photograph, what's behind you, behind
24 them, on the wall?
25 A. Well, it is a timeline of the changes we have made.

Page 72

1 MICHAEL R. REED
2 I think it is the same one that's in the paper you just
3 showed here.
4 Q. Now, if you would turn to page 436. This document
5 actually goes from 436 up to 457 -- excuse me, 451.
6 It's a copy of a July 2012 operating theater journal.
7 Are you familiar with that publication?
8 A. Yes, probably, yes.
9 Q. And if you turn to page 446 --
10 MR. ASSAAD: Objection, lack of established foundation for
11 use of this document in questioning the witness.
12 BY MR. GORDON:
13 Q. Is that you in that picture?
14 A. I think it is the same picture.
15 Q. Okay. And do you recall seeing this publication?
16 A. I saw it yesterday. I may have seen it at the time.
17 I don't -- I don't remember it. I remember the
18 photograph being taken, I think.
19 Q. Do you remember receiving an HAI Watchdog Award in 2011?
20 A. Yes. I think that's what he's got in his hand.
21 Q. Do you remember being interviewed by anybody about that
22 award?
23 A. Not explicitly, but it's -- it's not unlikely.
24 Q. How did the award come to be awarded to Northumbria?
25 Did it come out of the blue? Did somebody apply for it?

Page 73

1 MICHAEL R. REED
2 MR. ASSAAD: Objection. How is this award within the scope
3 of the McGovern paper?
4 THE EXAMINER: I don't understand, I confess, Mr. Gordon,
5 how what you have been doing for the last ten minutes
6 assists us with accurate dates at all.
7 MR. GORDON: Because I want to get back to the chart with
8 the dates, but I have got these --
9 THE EXAMINER: Where do you get a date that assists from
10 this page?
11 BY MR. GORDON:
12 Q. Well, let me ask you, Mr. Reed. Did you submit
13 an application for an award, an HAI Watchdog Award for
14 success for reducing infections?
15 MR. ASSAAD: Same objection.
16 A. So I may have done. It would have been me or the
17 nursing staff that did it, I imagine. I mean, we
18 applied for lots of awards over the years. That would
19 be not unusual.
20 BY MR. GORDON:
21 Q. Would you have expected that application to have
22 said: the only thing we did to reduce infections was to
23 change from forced air warming to the Hot Dog?
24 MR. ASSAAD: Objection, calls for speculation. Lack of
25 foundation.

Page 74

1 MICHAEL R. REED
2 THE EXAMINER: Do you remember what you included in the
3 application for the award?
4 A. I don't remember. I don't actually make any
5 application, but I may have done.
6 THE EXAMINER: Well, you may have done anything. We are
7 dealing with probabilities, rather than what may have
8 happened.
9 A. Yes. Well, it would have been made by me or by
10 Gail Lowdon, I imagine. Would we have said --
11 MR. ASSAAD: I would like a ruling. I don't think he should
12 answer that question, if he doesn't recall --
13 THE EXAMINER: No, fine. No, I am ruling that he does not
14 need to answer that question.
15 BY MR. GORDON:
16 Q. Was the only thing that you -- you won the award for,
17 was for changing the warming modalities, or were there
18 other infection control things that you did in the --
19 MR. ASSAAD: Objection, outside the scope.
20 THE EXAMINER: Let's get back to the documents, rather than
21 the award.
22 MR. ASSAAD: Ask him not to answer that question.
23 THE EXAMINER: That has no part within schedule B.
24 BY MR. GORDON:
25 Q. Did you change -- I will direct your attention to

Page 75

1 MICHAEL R. REED
2 page 425.
3 MR. ASSAAD: Sorry, what page?
4 MR. GORDON: The document is 425 through 431.
5 A. Yes, I have got that, yes.
6 BY MR. GORDON:
7 Q. And specifically page 427. Again, it says "Mike Reed as
8 a consultant orthopaedic surgeon." Do you see that?
9 A. (Nods.)
10 Q. Is this something you recall ever seeing before?
11 A. Well, I definitely saw it yesterday. I don't recall if
12 I have seen this before or not. It's obviously written
13 about me, rather than by me. Whether I would have
14 given -- been given the opportunity to sign it off,
15 I don't know.
16 Q. Well, do you recall being interviewed by the Clinical
17 Services Journal?
18 A. I don't think this was an interview. I think this
19 was -- this is based upon a presentation, I think,
20 rather than an interview.
21 Q. Okay.
22 A. I could be wrong, but that was my impression yesterday.
23 Q. Well, let's turn to page 453. The document goes from
24 453 through 457. Do you recognize that?
25 A. Yes.

Page 76

1 MICHAEL R. REED
2 Q. Okay.
3 THE EXAMINER: What is the JTO? Journal of Trauma and
4 Orthopaedics?
5 A. Yes.
6 BY MR. GORDON:
7 Q. You were one of the authors of this?
8 A. Yes.
9 Q. If you turn to page 454.
10 MR. ASSAAD: Just for the record: when you use these
11 documents, can you identify the Bates number, the title
12 of the document and establish foundation before asking
13 questions? Page number and title, so we know for the
14 record, so the record is clear and clean?
15 BY MR. GORDON:
16 Q. On page 454 in that box, that column, what are those --
17 under "Management", what are each of those items
18 contended to be?
19 A. So essentially there's risk factors for infection, so
20 this is identifying certain patient groups that are more
21 likely to get infections; so patients who are obese,
22 patients who smoke.
23 Q. Let's focus on the second --
24 A. And then perioperative factors. These are things maybe
25 that you can influence, as opposed to not.

Page 77

1 MICHAEL R. REED
2 Q. And you describe this as a summary table of common
3 prevention tactics; is that right?
4 A. Yes.
5 Q. And towards the bottom, you say you maintain
6 normothermia as one of the prevention tactics; right?
7 A. Yes, I think that's right, one of the ... yes.
8 Q. And your skin prep, you say you use an alcohol pre-wash,
9 followed by a 2 percent chlorhexidine-alcohol scrub; is
10 that right?
11 A. Whereabouts is that? Yes, okay. Well, that's what we
12 said.
13 MR. ASSAAD: I am going to object to the --
14 A. Actually, we said -- or betadine actually, so --
15 MR. GORDON: Okay.
16 MR. ASSAAD: Lack of foundation to his --
17 THE EXAMINER: Did you say lack of foundation? That is
18 fine. That is the standard objection made by U.S.
19 attorneys.
20 MR. ASSAAD: Okay. Well --
21 THE EXAMINER: They don't go on and explain the basis for
22 it, in my experience.
23 MR. ASSAAD: In depositions, no. But I say the --
24 THE EXAMINER: This is a deposition.
25 MR. ASSAAD: To be raised at trial.

Page 78

1 MICHAEL R. REED
 2 BY MR. GORDON:
 3 Q. Did there come a time when you switched the skin prep
 4 that you used at Wansbeck?
 5 A. Yes. It is on the timeline somewhere.
 6 Q. What did you switch from and what did you switch to?
 7 A. So we would have switched from a variety of things. It
 8 is surgeon preference. To -- I think we switched maybe
 9 at the end of 2010, the very end of 2010.
 10 Q. Do you recall there being a period of time that the
 11 laminar air system at Wansbeck required repair?
 12 A. Yes.
 13 Q. What was wrong with it?
 14 A. Well, this was -- it wasn't in all theaters, but in
 15 particular theaters, essentially it wasn't functioning
 16 properly.
 17 Q. How did you come to learn that?
 18 A. We had a guy come and assess it, an expert.
 19 Q. Was -- had you noticed some problem or was this
 20 a routine assessment?
 21 A. So I mean, I think as we made clear, we were trying to
 22 reduce the infection rates. We made a number of
 23 changes. We made -- you know, we were looking
 24 everywhere we could, trying to get a marginal gain on
 25 reducing infection rates. And that's the basis for

Page 79

1 MICHAEL R. REED
 2 getting them all checked.
 3 Q. Were any of the procedures in the Bair Hugger only
 4 period performed in the operating room that needed
 5 repair of the laminar airflow system?
 6 A. In truth, I am not sure when those dates are. It might
 7 be on the timeline; is it?
 8 Q. Did you have any hand in preparing the timeline?
 9 THE EXAMINER: I am sorry. I missed the question.
 10 BY MR. GORDON:
 11 Q. You --
 12 THE EXAMINER: I just did not hear it.
 13 A. Did I have a hand in preparing the timeline?
 14 THE EXAMINER: Right.
 15 A. Certainly over the years I have.
 16 BY MR. GORDON:
 17 Q. There's no way you can read the one in that -- in the
 18 article. So I took the liberty, for my sake, if you
 19 have -- of printing out a larger version of it.
 20 THE EXAMINER: How does this relate to the studies that we
 21 are concerned with?
 22 MR. ASSAAD: I agree.
 23 THE EXAMINER: I have not been able to have a copy that
 24 I can read.
 25 MR. GORDON: I understand that. I am going to pass you

Page 80

1 MICHAEL R. REED
 2 a copy that you can read.
 3 MR. ASSAAD: Can I have a copy that I can read?
 4 THE EXAMINER: If other counsel in the room could have
 5 a copy of it, so that they can read.
 6 MR. GORDON: Well, they are younger. They can probably read
 7 that one.
 8 MR. ASSAAD: I want the same copy that you are giving him.
 9 MR. GORDON: Okay. Well, I don't have it.
 10 THE EXAMINER: My question is: how does this relate to any
 11 of the studies with which -- to which this witness's
 12 evidence is confined?
 13 MR. GORDON: Mr. Dyer, with all due respect, this is a --
 14 THE EXAMINER: No, it is a simple question.
 15 MR. GORDON: Yes. And if you -- the timeframe that the
 16 Bair Hugger only was compared to the Hot Dog only, and
 17 resulting in a 74 percent reductions in infections,
 18 happens to coincide with a whole bunch of other
 19 infection control practices.
 20 THE EXAMINER: Why don't you put that to the witness?
 21 MR. GORDON: That is what I am trying to get to.
 22 THE EXAMINER: Dear God, we must have been trying to do it
 23 for about an hour now.
 24 MR. GORDON: Well, I am sorry I don't have the exquisite
 25 skills to go right to the point.

Page 81

1 MICHAEL R. REED
 2 THE EXAMINER: Well, then, get right to the point --
 3 BY MR. GORDON:
 4 Q. Is this the timeline you have been referring to, Mr.
 5 Reed? And we will mark this separately as, I guess,
 6 exhibit 5. So we will put copies in the record.
 7 (Exhibit Reed 5 marked for identification.)
 8 MR. ASSAAD: We have --
 9 THE EXAMINER: I am sure you do.
 10 A. Yes. I mean, I am sure this was produced in my
 11 department. I am not sure when or how up to date it is.
 12 I can't verify it. But I imagine it's correct there or
 13 thereabouts.
 14 MR. ASSAAD: Can we mark this as an exhibit, since we have
 15 produced this?
 16 THE EXAMINER: I think Mr. Gordon --
 17 MR. GORDON: I just said we will mark it as an exhibit.
 18 MR. ASSAAD: I am going to object to whatever exhibit this
 19 is, based on the lack of foundation. The witness has
 20 just said he didn't create it.
 21 BY MR. GORDON:
 22 Q. Just to clarify, and I think the record is clear. But
 23 did you -- were you involved in the creation of the
 24 timeline?
 25 A. I definitely have been involved in the creation of the

Page 82

MICHAEL R. REED

1 timeline over the years. It is a live document; that is
2 what I would say. So it's not fire and forget. It is
3 kind of updated as we go. So this is quite -- probably
4 quite a recent one.

5 Q. But maybe not the most recent one?

6 A. Yes.

7 MR. ASSAAD: Leading.

8 BY MR. GORDON:

9 Q. Was there a switch in your hospital's -- in the
10 antibiotic use for hip and knee replacement surgeries,
11 where you switched from cefuroxime to gentamicin?

12 A. Yes, so this is obviously made clear in the paper that
13 we wrote, with -- you know, this is based on caveats and
14 this is all in the paper that we wrote.

15 THE EXAMINER: Which paper are you referring to?

16 A. The McGovern paper.

17 THE EXAMINER: Right, okay.

18 A. The one that has got the clinical data, if you like.

19 These riders are clear in the paper that we have --

20 THE EXAMINER: Some of us haven't had the opportunity to
21 look at the paper before today at any time; so that is
22 why, Mr. Gordon, your route is somewhat unclear to me.

23 So you are saying the paper contains caveats as to
24 other matters that have changed during the period?
25

Page 83

MICHAEL R. REED

1 A. Yes.

2 THE EXAMINER: Thank you.

3 BY MR. GORDON:

4 Q. Is it correct that the cefuroxime was switched to
5 gentamicin in August 2007; is that correct?

6 A. The dates that are in the paper -- actually, that isn't
7 in the paper. That's beyond -- that's well beyond it.
8 That is before the paper. Yes, so that feels right.

9 Q. And is there any reference in the McGovern paper to the
10 hospital having switched from cefuroxime to gentamicin
11 in 2007?

12 A. I don't think so, but it's before the -- it's well
13 before the time period, isn't it?

14 Q. Well, there is a reference in the paper to switching
15 from gentamicin only to the lower dose of gentamicin and
16 adding teicoplanin?

17 A. Mm-hm, which was in the time period of the paper, of
18 the ...

19 Q. Well, the switch from cefuroxime to gentamicin, that
20 occurred before you started the Bair Hugger only period
21 that you were looking at; right?

22 A. Yes.

23 Q. So what -- and the gentamicin reduction and addition of
24 teicoplanin, is it correct that that occurred in the
25

Page 84

MICHAEL R. REED

1 beginning of March 2009?

2 A. The data in the paper, if you've got the paper there in
3 front of you, then that will be right.

4 Q. Okay.

5 THE EXAMINER: Just remind me where the McGovern paper is?

6 MR. HOLL-ALLEN: 540.

7 THE EXAMINER: Thank you.

8 MR. HOLL-ALLEN: There are details of the changes in the
9 antibiotic regime at 543, reflected in the column ...

10 MR. GORDON: Thank you.

11 BY MR. GORDON:

12 Q. So when did the switch from gentamicin only to
13 gentamicin plus teicoplanin take place?

14 A. So from July 2008 to February 2009, a single dose of
15 gentamicin was given, 4.5 milligrams per kilogram.

16 In March 2009, this was changed to teicoplanin,
17 400 milligrams, and gentamicin, 3 milligrams per
18 kilogram. And then I go on to talk about the gentamicin
19 and the cement.

20 THE EXAMINER: The gentamicin, briefly, is ...?

21 A. It is an antibiotic which is effective against many of
22 the bacteria that cause infections.

23 BY MR. GORDON:

24 Q. And in fact, though, you have said it should not be used
25

Page 85

MICHAEL R. REED

1 as a prophylactic -- by itself as a prophylactic
2 antibiotic in hip and knee arthroplasties; correct?

3 A. So the main reason for our switch, in fact, was renal
4 failure; because it is a high dose of gentamicin that we
5 were having to give, 4.5 milligrams per kilogram. And
6 that was, we felt, damaging a proportion of our
7 patients. So we switched to gentamicin because we had
8 to move -- we had to stop using cefuroxime. That
9 became, if you like, almost illegal in the U.K., to
10 use --

11 THE EXAMINER: To use?

12 A. The cefuroxime change in 2007 was driven by the NHS, the
13 big NHS, if you like, and it's because it has
14 an association with Clostridium difficile infection. So
15 the big NHS --

16 THE EXAMINER: I think that is a terminology that is
17 familiar in this country, but not necessarily to the
18 U.S. attorneys. Could you repeat that?

19 A. So it is a diarrhoeal infection which is associated with
20 antibiotic use. And there is a big government campaign
21 to reduce Clostridium difficile rates, a bit like MRSA
22 maybe in the United States. So the executives of the
23 trust are charged with reducing rates of Clostridium
24 difficile. One of the ways of doing that would be to
25

Page 86

1 MICHAEL R. REED
 2 stop using cefuroxime in the hospital. So that's what
 3 happened to us back in 2007.
 4 THE EXAMINER: So that came from above?
 5 A. It was driven from above.
 6 THE EXAMINER: But your change to a gentamicin mix, what,
 7 came from active patient experience?
 8 A. Yes. So there was two things. We -- we have written
 9 a paper on this, which is probably somewhere in there.
 10 But that, from memory, showed an increase in infection
 11 rates and an increase in renal failure rates; and
 12 a significant reduction in Clostridium difficile,
 13 reduced by three patients.
 14 BY MR. GORDON:
 15 Q. Are you talking about the switch from cefuroxime to
 16 gentamicin; it reduced the Clostridium difficile, but
 17 you had an increase in infection and ...?
 18 A. Yes, I don't know -- I genuinely don't know, but I am
 19 sure you have got the paper, whether we had an increase
 20 in infection, but I am sure it was in that direction.
 21 It wasn't significant.
 22 Q. Take a look at pages 527 through 531.
 23 And it is in the abstract, the findings. Can you
 24 just summarize them?
 25 MR. ASSAAD: Objection. I just want to be clear. Based on

Page 87

1 MICHAEL R. REED
 2 Mr. Jonathan's objection earlier on about using
 3 documents that are not part of the scope of this, you
 4 know -- the scope of this sealed order. Are we saying
 5 he is allowed to go to other documents by the --
 6 THE EXAMINER: Well, yes, because he is -- as I understand
 7 it, because I have not had the opportunity to read the
 8 McGovern paper, so I don't know what its conclusions
 9 are. But as I understand it, Mr. Gordon is seeking to
 10 establish other operative factors during the relevant
 11 period. Do I have that right, Mr. Gordon?
 12 MR. GORDON: Yes.
 13 MR. ASSAAD: I just want to be clear, based on what Mr.
 14 Holl-Allen was saying earlier about other documents.
 15 THE EXAMINER: If Mr. Holl-Allen will point us to
 16 a different one.
 17 MR. HOLL-ALLEN: It was --
 18 A. So in summary, there was what would be said to be
 19 an insignificant fall in Clostridium difficile rates,
 20 although very close to significance. But there was
 21 an increase in pneumonia, which -- cefuroxime probably
 22 protects the chest; that's why that happened. Renal
 23 failure, which required critical care admission and
 24 return to theater, and return to theater for infection.
 25 BY MR. GORDON:

Page 88

1 MICHAEL R. REED
 2 Q. That RTT for proven infection; what does that mean?
 3 A. Return to theater for proven infection increased.
 4 Q. And what did it go from and to?
 5 A. Well, 0.66 to 1.52.
 6 Q. So it went from 0.66 percent infection to 1.52 percent
 7 infection when you switched from cefuroxime to
 8 gentamicin by itself; am I reading that right?
 9 A. Yes.
 10 Q. And that switch occurred prior to the start of the
 11 Bair Hugger only period; is that right?
 12 A. That switch occurred, yes; the switch from cefuroxime to
 13 gentamicin, yes. The switch beyond that occurred in --
 14 as we have said in the paper, occurred during the Bair
 15 Hugger period.
 16 Q. And, well, the switch occurred, I thought you -- at the
 17 end of -- you were using gentamicin only up until
 18 February 28, 2009; is that right?
 19 A. Well again, that's in the McGovern paper, when we
 20 changed. There is detail on that.
 21 Q. And if you start at the McGovern -- the Bair Hugger only
 22 period in the McGovern, on 1st July, 2008, that would
 23 mean July, August, September, October, November,
 24 December 2008, February and March of 2009?
 25 THE EXAMINER: No, January and February, I think.

Page 89

1 MICHAEL R. REED
 2 BY MR. GORDON:
 3 Q. What did I say?
 4 THE EXAMINER: It started -- it ended on 1st March.
 5 BY MR. GORDON:
 6 Q. January and February. I will do that again.
 7 July, August, September, October, November,
 8 December, 2008. January 2009, February 2009; eight
 9 months.
 10 For eight months of the Hot Dog only period, the
 11 only antibiotic that was being given to patients was
 12 gentamicin; correct?
 13 A. Yes. That sounds plausible.
 14 Q. And --
 15 A. That's written in the paper.
 16 Q. Once you switched to a combination of gentamicin and
 17 teicoplanin, were there any further changes to the
 18 antibiotic regimen through the remainder of the study
 19 period?
 20 A. So we changed from gentamicin to gent/teic. That was
 21 the change we made.
 22 Q. And that remained the same through the remainder of the
 23 balance of the study period; is that right?
 24 A. Yes. It is the same today.
 25 Q. Yes. Was there -- wasn't there a point in time after

Page 90

MICHAEL R. REED

the study period, where you actually lowered the gentamicin further or increased the teicoplanin a little ...? It doesn't matter. I am not going to --

A. I don't think so.

Q. Obviously that is beyond -- that is beyond the scope, I think.

A. It's 3 milligrams per kilogram that we used. That's what we've always used, I think.

Q. Okay. During the seven months of the Hot Dog only period, what antibiotic regimen was used?

A. Gent/teic.

Q. So all of the Hot Dog patients, Hot Dog only patients, had the combination of gentamicin and teicoplanin; is that correct?

A. Mm-hm.

Q. And for eight months of the 20 months of the Bair Hugger only period, Bair Hugger only patients had only gentamicin; right?

A. I mean, I am not sure about the exact dataset in evidence, but certainly there was a period when -- during that Bair Hugger phase, if you like, where one group was on the antibiotic gent, and one was on gent/teic. That is in the paper.

Q. Right. And there were 12 months of the Bair Hugger only

Page 91

MICHAEL R. REED

period where the Bair Hugger patients were receiving the same antibiotic regimen as the Hot Dog only patients were; correct?

A. Sorry, say that again?

THE EXAMINER: What period was that?

BY MR. GORDON:

Q. From March 1st, 2009 until the end of the Bair Hugger only period. That was the same gentamicin and teicoplanin that continued on into the Hot Dog period?

A. That feels right, yes.

Q. So it's only the -- the first eight months of the Hot Dog only period, where there was a different antibiotic regimen?

A. Do you mean the Bair Hugger only period?

Q. I mean the Bair Hugger only period, yes.

A. Well, again, I would need a bit more time to work out exactly how many months. But you're right, in principle, in that there was a period in the Bair Hugger group when you are on the gentamicin and a period when you are on the gent/teic.

THE EXAMINER: Is that right? As I understand it, the change to gent/teic occurred right at the end of the Bair Hugger only period, but at the beginning of the transition period.

Page 92

MICHAEL R. REED

MR. GORDON: No, I think it is a year on.

MR. HOLL-ALLEN: Yes. The transition period was beginning in 2010.

THE EXAMINER: Oh sorry, I apologize. I'll withdraw that. Sorry, that explains my confusion.

BY MR. GORDON:

Q. In addition to the change in the antibiotics you also changed the venous thromboprophylaxis regimen; right?

A. (Nods.)

Q. You need to say "yes" or "no", just to ...

A. Yes, yes.

Q. What was that change?

A. So again, I wouldn't be able to cite dates for you, but we went for a period on rivaroxaban, which again is in the McGovern paper. We have put the dates in there. And yes, we had an increase in our return to theater rates when we were using that, and we published that.

Q. And what happened? Did you continue with the rivaroxaban or change to something else?

A. Yes, we changed to tinzaparin; something else, yes.

Q. What were you using before you changed to rivaroxaban?

A. Heparin, I think. I am not entirely sure.

Q. I don't want to -- I am not trying to test your memory. If you go back to the paper on page 540 through 547 --

Page 93

MICHAEL R. REED

if you --

THE EXAMINER: You have got about five minutes left on the tape.

BY MR. GORDON:

Q. Let's see if we can at least pin down the thromboprophylaxis change.

We have the -- before you switched to rivaroxaban, you were using tinzaparin; right?

A. Yes.

Q. You switched to rivaroxaban for a seven month period; right?

A. Yes, that feels right.

Q. And then went back to tinzaparin; right?

A. Yes.

Q. What were the months that you switched from tinzaparin to rivaroxaban?

A. Well, I think as you said, August 2009 to February 2010. That's when we were on rivaroxaban.

Q. So that would be August, September, October, November, December of 2009. January, February 2010. Seven months of rivaroxaban; is that right?

A. Yes.

Q. And those seven months occurred solely in the Bair Hugger only period; right?

Page 94

MICHAEL R. REED

A. It may be six months, but yes.

Q. And you switched from tinzaparin to rivaroxaban, why?

THE EXAMINER: Sorry, are you asking about the first switch?

MR. GORDON: Yes, the first switch.

THE EXAMINER: Okay.

A. I am not sure why we switched. I mean, I think it's -- it's an oral treatment, so you can have a tablet, rather than injections. So there's an advantage for the patients and maybe for compliance. That would be the rationale, if you like, for switching.

BY MR. GORDON:

Q. And regardless of the rationale for switching to rivaroxaban, you switched back after six or seven months, because of all the complications with rivaroxaban; right?

A. Because they were bleeding essentially, yes.

Q. And returning to theater; correct?

A. Yes.

Q. And --

THE EXAMINER: Rectal bleeding?

A. No, just bleeding from the wound.

THE EXAMINER: Oh right.

A. Well, and bleeding into the wound specifically. So they were getting what we call hematomas. So collections of

Page 95

MICHAEL R. REED

blood that just continued to leak and cause trouble.

THE EXAMINER: So after six or seven months, it would have been sufficient to justify a change back; that must have been a fairly marked sequence of events?

A. Yes. I mean, well, we certainly -- we picked it up. And we weren't the first. In fact, subsequently there were ten other trusts, and I think you have got that paper in there, that had that issue. And internationally as well, since then.

THE EXAMINER: Shall we change the tape?

MR. GORDON: Yes. Let's do that.

THE VIDEOGRAPHER: This is the end of tape number 1, in the deposition of Michael Reed. We are going off the record at 2:28.

(2:28 p.m.)

(Break taken.)

(2:37 p.m.)

THE VIDEOGRAPHER: This is the beginning of tape number 2, in the deposition of Michael Reed. We are going on the record at 2:37.

THE EXAMINER: Yes.

BY MR. GORDON:

Q. Mr. Reed, I am not sure where we were. What was the period of rivaroxaban; what were the months?

Page 96

MICHAEL R. REED

A. So from August 2009 to February 2010, rivaroxaban was provided from Day 1 post-operatively.

Q. Was it at the beginning or at the end of February?

A. I couldn't tell you from here. I mean, we would have that somewhere.

Q. It says "in February", but ...

A. Sure, I appreciate that. Based on what I have got in front of me, I can't remember.

THE EXAMINER: "In February" suggests a change some time during the month, as opposed to at the beginning or at the end, doesn't it?

MR. GORDON: Well --

THE EXAMINER: Perhaps we can --

MR. GORDON: Let's look at another paper.

BY MR. GORDON:

Q. If you turn to page 521 through 525, that's -- is that the paper you were referring to earlier, where you were the co-author about the switch to rivaroxaban?

A. (Nods.)

Q. If you look on page 522, the first very full paragraph, it says:

"Group 2 had their primary operation between 1 August, 2009 and 28 February, 2010."
Seven months.

Page 97

MICHAEL R. REED

A. (Nods.)

Q. So would that be the rivaroxaban only period?

A. On the basis of what we have here, yes, I think it would, yes.

Q. Okay.

Well, I have been trying to track this now, over the chart. The Bair Hugger only period went from July 2008 to the end of February 2010. The transition period was March, April, May of 2010 and then the last seven months of 2010 was the Hot Dog only.

Now, in the comparison between Hot Dog and Bair Hugger, you didn't use the three months of the crossover; right?

A. Correct.

Q. Okay.

So the surgical site infection rate for the Bair Hugger only included eight months where you were using gentamicin only; right?

A. Okay.

Q. And it included seven months where you had switched from tinzaparin to rivaroxaban; right?

A. Okay.

Q. And those two periods actually didn't coincide. In other words, the switch -- the antibiotics switch to

Page 98

MICHAEL R. REED

gentamicin plus teicoplanin had occurred prior to the rivaroxaban?

A. I will take your word for it. I am sure you have got the data -- you have got the advantage of having mapped it out. I can't think of ...

Q. Well, I'm more than happy -- if you want to see my scribble, or you can map out for itself.

A. I don't disagree with what you're saying. I'm sure you have got that ...

Q. Just those two factors, the antibiotic and the proper(?) thromboprophylaxis or the common(?) thromboprophylaxis. There were five months during the Bair Hugger period when the Bair Hugger patients had the same antibiotic regimen and thromboprophylaxis regimen, as in the seven months of the Hot Dog period; right? That being March of 2009 to the end of July 2009?

A. I cannot think that fast, I am afraid, but you are probably right.

Q. Well ...

A. So are you saying that there was a crossover when they had rivaroxaban and gentamicin; is that what you are saying?

Q. No, there wasn't; was there?

A. Well, I don't know. You have got the data there.

Page 99

MICHAEL R. REED

Q. We spent a lot of time on this. The gentamicin only period, for Bair Hugger, was from July 2008 to the end of February 2009; but the rivaroxaban switch did not start until August 2009 and ended in February of 2010, and there was no overlap.

A. Okay.

Q. So there are two discrete periods; right?

A. Right. Sounds fair.

Q. But both those discrete periods occurred in the Bair Hugger period?

A. Yes.

Q. But there was five months in the middle essentially of the Bair Hugger only period, when the Bair Hugger patients were getting the same antibiotics and the same thromboprophylaxis as the Hot Dog only patients got?

MR. ASSAAD: Objection, leading.

A. Was there? Weren't they on different antibiotics?

BY MR. GORDON:

Q. Okay. What antibiotics were the Bair Hugger patients on in March to July 2009?

A. I am going to have to go back to the paper. We could just map this out and ...

Q. Well, how about -- why don't you map it out. So that's your conclusions. Yes.

Page 100

MICHAEL R. REED

A. Do you want me to borrow your sheet where you have written it all out or ... just in the interests of time?

Q. Well, I would love to, but I know I am going to get an objection.

THE EXAMINER: Well, if we had clean copies of the chart on page 546, which I understand are in the plaintiffs' bundle, it would make everyone's life much easier, wouldn't it?

MR. GORDON: Right, but I am getting huge objections on foundation for that, so I --

MR. ASSAAD: I have no objection if you want to use my copy.

THE EXAMINER: He can't object to a document that they have included in their bundle.

MR. ASSAAD: And I would never make an objection.

A. Do you want me to go to that?

MR. ASSAAD: We have a clean copy in our --

MR. GORDON: Oh, I see what you are saying. Oh yes. I don't have an objection to that.

MR. HOLL-ALLEN: Do you want to take my page?

A. Thank you.

MR. HOLL-ALLEN: I am supplying the witness with page 1543 of the McGovern article, which corresponds with page 546 in the marked copy.

THE EXAMINER: Okay. And what is it, Mr. Gordon, you want

Page 101

MICHAEL R. REED

him to mark on it?

MR. GORDON: I guess we will have to mark this as a separate exhibit, if he is writing on it. So this could be exhibit 6.

(Exhibit Reed 6 marked for identification)

BY MR. GORDON:

Q. If you could just draw the line, draw a line indicating when the -- you switched from gentamicin to gentamicin plus teicoplanin.

A. Just excuse me. I am just going to draw the rivaroxaban because I have got the page, to save us time.

Q. Perfect.

A. And then the next one was the gentamicin switch.

Q. Yes.

A. The McGovern paper. Could you give me a page for that? Just give me the ...

MR. ASSAAD: So 543, I think is the information; the left hand column.

A. 543.

MR. GORDON: Yes.

A. Actually, I can just copy it off here.

THE EXAMINER: This is what he was being asked to do, as I understand it, as well.

MR. GORDON: I think page 543 does give the --

Page 102

MICHAEL R. REED

THE EXAMINER: What are you looking for, Mr. Reed?

MR. GORDON: The antibiotic switch dates.

A. The antibiotic switch dates. So --

BY MR. GORDON:

Q. In the middle of that first paragraph?

A. So in February 2009, they switched.

Q. Well, it looks like it says that in March 2009, this was changed to teicoplanin 4 milligrams and gentamicin 3 milligrams per kilogram.

A. Yes, okay. My chart looks like that. Is that what you are expecting?

Q. Yes. And you -- based on what you have done now, is there a period of time in the Bair Hugger only time period, when the Bair Hugger patients were receiving the same antibiotics and the same thromboprophylaxis as the Hot Dog patients?

A. Yes.

Q. What was that period?

A. Well, it's from February 2009 till July 2009.

Q. Five months?

A. So it was March, April -- no, it wasn't. It was February, March, April, May, June. Five months.

Q. Okay. So if you had compared the SSI rate for that five month period, in the middle of the Hot Dog only period,

Page 103

MICHAEL R. REED

to the seven month Hot Dog -- excuse me. Did I say Hot Dog?

If you had compared the five months in the Bair Hugger only period, when the same antibiotic and thromboprophylaxis regimens were used, to the seven months of the Hot Dog period, then you would have eliminated the possibility that the differences you were seeing could have been influenced either by the antibiotics or the thromboprophylaxis; correct?

MR. ASSAAD: Objection, lack of foundation, misstates the prior testimony. Assumes facts not in evidence.

THE EXAMINER: You may answer.

A. It would be a pretty small series to compare, but you could compare them, yes.

BY MR. GORDON:

Q. In your rivaroxaban study, what was the period of time of the series that you compared?

A. Could you tell me that?

So ...

Q. It looks to me like it was six months versus seven months.

A. Okay. Bearing in mind there is a different end point he is looking for. He is not looking for infection as an end point.

Page 104

MICHAEL R. REED

Q. Did you assess infection in the rivaroxaban study?

A. We did, I think, assess infection.

Q. And --

A. My recollection is: there was no difference in the infection rates.

Q. Let's take a look at that. That is an important point. 521 through 525?

A. There was no significant ...

THE EXAMINER: Where are we looking now?

MR. GORDON: The rivaroxaban study.

THE EXAMINER: Which is page what?

MR. GORDON: 521 through 525.

BY MR. GORDON:

Q. If you look at 523, the very last paragraph on that page, where it says:

"Our rate of infection increased from 1 percent to 2.5 percent, following RBC ... following the introduction of rivaroxaban and infection rate of 1 percent is similar to that reported in the literature following hip and knee replacements."

Did I read that correctly?

A. Yes.

Q. And the six month period that you compared the rivaroxaban to -- or the six month tinzaparin period

Page 105

MICHAEL R. REED

where you found a 1 percent infection rate, that you said was similar to that reported in the literature following hip and knee replacement, that six month period in your rivaroxaban study coincides with five of the six months of the Bair Hugger only period, where the antibiotics and the thromboprophylaxis was the same. There is one month difference; right?

MR. ASSAAD: Objection, lack of foundation. Misstates the document.

THE EXAMINER: Is that correct?

A. Could you repeat that for me? I am sorry. I am not picking up on exactly what you are saying there, so ...

BY MR. GORDON:

Q. The period of time that you -- in your rivaroxaban study.

A. Yes.

MR. ASSAAD: Which one are you referring to? Because there's two.

MR. GORDON: 521 through, whatever, 525.

BY MR. GORDON:

Q. Actually, page 521.

"Between February 2009 and February 2010, all patients who underwent(?) THR/TKR in our hospital ..." And there you were using a 30 day period instead of

Page 106

MICHAEL R. REED

60 days for follow-up; right?

A. Okay. If that's what it says, yes.

Q. So the first six months of the rivaroxaban comparator was tinzaparin only; and that was February 1st, through the end of July 2009; right?

A. Yes.

Q. And that coincides with five of the six months of that period of Bair Hugger, when the same antibiotic regimen and thromboprophylaxis regimen was being used?

A. Yes.

Q. As in the Hot Dog only period.

So in that six month timeframe in your rivaroxaban study, you found a 1 percent infection rate. In the next seven months of rivaroxaban, which was also during the Bair Hugger only period, the infection rate jumped to 2.5 percent and then you went back to tinzaparin; right?

A. Yes. So what is clear in the rivaroxaban paper is that there is no significant difference in infection rates. I think that was what it showed. It wasn't far off significance, I will give you that; but if you -- we couldn't link rivaroxaban to infection.

Q. Who did the statistical analysis for your rivaroxaban paper?

Page 107

MICHAEL R. REED

THE EXAMINER: "For your"; which ...?

MR. GORDON: The rivaroxaban paper.

MR. ASSAAD: There's two of them. Can we be clear which one we are talking about?

MR. GORDON: The one we are looking at. The one from page 521 to page 52 -- whatever. You can ask him about another paper later.

MR. ASSAAD: You have a paper right after that, sir. That is the same thing.

THE EXAMINER: We are on 521 to 525. We will stay on there until we move.

A. I don't know. I was not lead author on that. I don't know.

BY MR. GORDON:

Q. Okay. And when you say it is not statistically significant, the jump from 1 percent to 2.5 percent, it had a P value of 0. -- 0.102. So you are saying that didn't meet the test for statistical significance.

A. Yes. So it doesn't meet, if you like, the sort of accepted test; although in reality, it is a continuum, I accept that. So ...

Q. And from a clinical standpoint, jumping from 1 percent to 2.5 percent --

A. Sure.

Page 108

MICHAEL R. REED

Q. -- in a short period of time like that was sufficiently concerning that you switched back?

A. Yes, that's --

MR. ASSAAD: Objection, leading.

A. That's why we put it in the paper. That's why we referred to it in the McGovern paper.

BY MR. GORDON:

Q. Okay. And the 1 percent timeframe, 1 percent infection rate, covers that five month window in the middle of the Bair Hugger period, that you could compare apples to apples, at least with respect to thromboprophylaxis and antibiotics; correct?

MR. ASSAAD: Objection, leading.

A. I think, yes. I think on the basis of what you are saying, that is a reasonable thing. The groups are very small, then. You can't -- it is easier to compare a big group to a small group than it is a small group to a small group, when you are looking at the significance of testing.

BY MR. GORDON:

Q. Well, it would be even bigger to compare a big group to a big group; right?

A. Yes.

Q. Was there a period of time when you adopted some sort of

Page 109

MICHAEL R. REED

a color coding system in the OR, in terms of what people wore?

A. Yes.

Q. What was that? What was the purpose of that?

A. So we -- essentially when you are in theater, you wear purple, what we would call scrubs, so the sort of pajamas. When you are out of theater, you wear blue. And it's just a way of making sure that people don't go out of theater and contaminate people on the ward and vice versa.

Q. Was there --

THE EXAMINER: Are there changing facilities before you leave the operating theater area?

A. Yes.

BY MR. GORDON:

Q. Was there some change in the footwear that occurred?

A. Yes. So we made lots of changes, as we have detailed here.

Q. When you say "As we have detailed", are you talking about the McGovern paper?

A. So you mean, there's presentations in here. There's papers we have written on it and ...

Q. And the reason I am asking about the McGovern paper is that you say on page 546:

Page 110

MICHAEL R. REED

"This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example ..."

THE EXAMINER: Where are we?

MR. GORDON: Page 546.

THE EXAMINER: Yes, but where?

BY MR. GORDON:

Q. On the left hand side, the first full paragraph that begins:

"This study does not establish a causal basis ..."

But you say:

"For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010."

And my -- I am emphasizing the words "For example". You've got thromboprophylaxis and antibiotics specified in here.

But my question is: are there -- did I miss it or are there any other places within there, where you actually -- within the McGovern paper, where you talk

Page 111

MICHAEL R. REED

about what other changes had occurred or when?

A. So we did -- we obviously listed that there were changes, so we chose two specific ones, because they are the ones really with the evidence base or the concern around them.

So to turn that on its head, if I was to say, you know: we changed the color of theater blues in the article here on infection, they would say: well, where is the evidence for that, that influence? And you wouldn't find a reference for that either.

So a lot of the things we have done are on the basis of common sense, rather than evidence that it will help infection. I would accept that.

Q. Did you change the dressings?

A. That's -- at one point we changed the dressings, yes.

Q. From what to what?

A. So I am struggling to think if we had a policy before we changed, in terms of -- I think it was probably certain preference. But after we changed, it was to something called Aquacel Surgical.

Q. Is that the same thing as Jubilee?

A. Jubilee, yes. Jubilee is --

Q. The hospital?

A. The hospital that invented it. The Golden Jubilee.

Page 112

MICHAEL R. REED

Q. Was there any evidence to support switching to the Jubilee dressing?

A. So they had evidence.

THE EXAMINER: "They" being?

A. The Golden Jubilee had done a small trial on it.

BY MR. GORDON:

Q. The hospital in Glasgow?

A. Yes.

Q. What did their trial demonstrate?

A. So they looked at a variety of outcome measures, but the ones I remember were blister rates. So you can sometimes get blistering around a wound. And they were reduced with that dressing, and infection rates were reduced. I can't remember whether that was superficial and deep or whether it was just deep. But there was a -- there was an effect.

Q. And when did you switch to the Jubilee dressing?

A. It's probably on the timeline, I think.

Would you care to point it out, to speed me up?

There is a lot on here.

Q. If I am reading correctly, it is the October 2009.

THE EXAMINER: Right at the bottom left hand side, at the bottom, in the yellow box.

A. Okay. So ...

Page 113

MICHAEL R. REED

THE EXAMINER: Well, that's audit.

A. Yes, it's audit. I am not quite sure what that means.

It may well have changed well ahead of that. There is another wound dressing audit you see underway, I think, at the beginning of 2008.

THE EXAMINER: I see, yes.

A. So I couldn't say with any certainty when we changed, but it was a pretty early change, I think, that we made.

BY MR. GORDON:

Q. Would it have been before or after the audit?

A. Well --

THE EXAMINER: You can't audit something you are not using.

A. No, so I mean, I think -- I am struggling to know whether in quarter 1 2009 we introduced it or whether it was before that. I don't know.

BY MR. GORDON:

Q. Okay. But it was before --

A. It probably is written somewhere in your documents.

Q. It was before the switch to Hot Dog; right?

A. I mean, my recollection is that it was, but I couldn't say with any certainty.

Q. Did there come a point in time when, at Wansbeck, you started screening hip and knee patients for methicillin resistant staphylococcus aureus, MRSA?

Page 114

MICHAEL R. REED

A. No. We have always done that, but I think you are alluding to sensitive staph aureus.

Q. That was my next question. So you have always done the first screening?

A. Yes, I can't remember when we didn't.

Q. But my next question -- yes. So did there come a time when you -- was there a time when you had not been screening for methicillin susceptible staphylococcus aureus, and you started screening for that?

A. So that was in early 2010, I think we started screening for that.

Q. And was it just screening, or did somebody who had -- did you take some action?

A. So we would decolonize patients to -- essentially what you are trying to do is to reduce the load of this particular bug in someone's nose or on their hands or whatever.

Q. So some of the Bair Hugger only patients would have not had the benefit of MSSA screening; some of them would have? Either way -- did you say February 2010?

A. I think it was January, but ...

Q. Okay. So at the very end of the Bair Hugger only period?

A. Yes.

Page 115

MICHAEL R. REED

Q. So if you were the Bair Hugger -- some of the Bair Hugger patients at the very end would have had MRSA screening and all of the Hot Dog only patients had the benefit of MSSA screening?

A. That is due. But what I would say is that there is no evidence that it reduces infection rates in this group; certainly at this point. That may not be the case now, six years down the line. But yes, it was introduced with that intention.

Q. Did there come a point in time when you instituted pre-warming of patients for hip and knee ...?

A. Yes.

Q. When was that?

A. It will probably be on the timeline.

THE EXAMINER: What does it mean?

A. So essentially, if you warm someone up before their operation, then they are less likely to get cold during their operation. If you are less likely to get cold during the operation, then it reduces your complications of bleeding, heart attacks and perhaps infection.

BY MR. GORDON:

Q. Well, had you seen any studies before you implemented the pre-warming, to address that specific issue; does it have any impact on infection?

Page 116

MICHAEL R. REED

A. So it does have an impact on infection. But I think what's less certain is whether it has an impact on infection if you warm them in theater as well. So isolated pre-warming has an impact on infection.

In fact, David Leaper, who you are going to meet, published that in a very good large study. But my recollection is that those patients weren't warmed during surgery.

Q. Are you talking about the Melling paper from 2001?

A. Yes.

Q. Was there a study closer in time, so when you switched to pre-warming that you had seen ...?

A. So I have certainly seen a study that shows that if you pre-warm people, they are less likely to get cold, so that's like a proxy. So I have certainly had that in some of my presentations.

Q. Have you ever indicated that in your presentations, that you read the New England Journal and found some article about a significant reduction in infection rates by adding pre-warming, and then you decided to do that as part of your routine procedures?

MR. ASSAAD: Objection, leading.

A. That was David Leaper; David Leaper's study, I think. I think that was in the Lancet, actually, David Leaper's

Page 117

MICHAEL R. REED

study. Is pre-warming in the New England Journal of Medicine? I am not aware of that.

BY MR. GORDON:

Q. Okay. I am not going to take time going into too many more ...

A. There is now good evidence evolving, but it is coming into practice as a definite now, compulsory. This is six years down the line.

Q. When did you start pre-warming patients?

A. It is probably on the timeline. Can you point that out for me?

Q. I think it is probably the second quarter of 2010.

A. Okay. It is likely to be correct if it is on here.

THE EXAMINER: Yes, it is part of the entry in the yellow box.

BY MR. GORDON:

Q. The yellow box up on the top bit.

A. Yes, I am not sure that the Lancet study -- and I am genuinely not sure. But I think that is not based on the people who are warmed during the operation as well. I think in David's study, they were only pre-warmed.

Q. The 2001 Melling --

A. Yes.

THE EXAMINER: So in your hospital, as from June 2010 they

Page 118

MICHAEL R. REED

were both pre-warmed and warmed during the operation?

A. Yes, yes. And the major benefit of that would be reducing bleeding, reducing anxiety, reducing pain perhaps as well, reducing transfusion rates. It has a lot of advantages. It does not relate specifically to infection and I am not sure that warming and pre-warming together reduce infection rates. Either is probably fine.

BY MR. GORDON:

Q. Now, at some point you switched to chlorhexidine as a skin prep; is that right?

A. (Nods.)

Q. When was that?

A. In my recollection, late 2010, right at the end of the -- I will save you some time. Right at the end of the -- actually, I can't remember which period it was.

THE EXAMINER: Look at the little red box for Q4/2010.

A. Okay, there you go, right. At the end of 2010. So -- yes.

BY MR. GORDON:

Q. Did there come a point in time when you instituted a root cause analysis of infections?

A. Yes. I think that was pretty early on, actually.

Q. Like the first quarter of 2009?

Page 119

MICHAEL R. REED

A. Yes, or even before that, I suspect, actually.

THE EXAMINER: It says "underway", which is not exactly very precise.

BY MR. GORDON:

Q. I just want to cut to the chase. Would you agree that there were -- that there was, first of all, a serious problem with infections in the knee and joint area, in the late 2008/early 2009 timeframe?

MR. ASSAAD: Objection to form, argumentative.

THE EXAMINER: You may answer.

A. So I mean, I would definitely agree, we were trying to reduce our infection rates. And it's a devastating complication and we were trying to reduce them. And you know, I think as we have made very, very clear publicly, we have tried lots of things to reduce it.

BY MR. GORDON:

Q. And over a period of time, you implemented a whole variety of infection control procedures?

A. Yes.

Q. And it wasn't just switching from Hot Dog -- or from Bair Hugger to Hot Dog; right?

A. So in the time period that we have put in the paper, I don't think there's anything significant that we haven't mentioned in the paper, which is the gentamicin

Page 120

MICHAEL R. REED

and the rivaroxaban, in terms of -- in terms of affecting infection rates.

You know, there are other things like MSSA screening which was introduced.

But at the time of this paper and still, there is no evidence to say that it reduces infection rates, staph aureus infection rates in joint replacement patients. Now, we are doing a piece of work now that does actually, I think, show that. But that is not in the literature at all, even six years down the line.

Q. Just looking at the timeline and the picture of you standing in front of that thing, the graph that starts out very high and goes down very quickly. Was that reflective of what was happening to the SSI rates?

A. So I mean, this chart is the SSI rates, but it is not -- you need to understand, it is not the Wansbeck primary joint replacement infection rates. This is --

Q. The whole system?

A. -- the conglomerate of superficial and deep revision, hip fracture patients, hemiarthroplasties, DHSs, and it is a large group. And the value of that is that you can make a change and hopefully track the advantage of that.

Q. There came a point in time when you stopped using one particular operating theater; correct?

Page 121

MICHAEL R. REED

A. Yes.

Q. Why was that?

A. That was, I think here.

Q. I think it was a little later in time.

A. The laminar flow repaired in Wansbeck. Is that the one you ...

Q. And that was when? That was -- it is kind of hard to tell from the timeline, other than that it was --

A. That was quarter 3/2008. Quarter -- at the start of quarter 3.

Q. Now, I --

A. To June 2008.

Q. From memory, I think it is in the orange box on the far right.

A. Okay.

Q. After the --

THE EXAMINER: That is Q4 of 2013, theater 2, WGH, closed to all TKH joint replacements.

A. Yes, so there was a brief period. That is not actually my theater, but there was a brief period that it was closed.

BY MR. GORDON:

Q. Okay. It was not a permanent closure? I don't want to talk about that, then.

<p style="text-align: right;">Page 122</p> <p>1 MICHAEL R. REED</p> <p>2 THE EXAMINER: Before we go on, the air conditioning,</p> <p>3 whatever you have done --</p> <p>4 MR. HOLL-ALLEN: Have I made it worse?</p> <p>5 THE EXAMINER: I heard it behind me cease to come out of the</p> <p>6 vents.</p> <p>7 (Off the record remarks.)</p> <p>8 THE VIDEOGRAPHER: Going off the record at ten past 3.</p> <p>9 (3:11 p.m.)</p> <p>10 (Break taken.)</p> <p>11 (3:11 p.m.)</p> <p>12 THE VIDEOGRAPHER: Back on the record at 3:11.</p> <p>13 THE EXAMINER: So you want to go to volume 4 now?</p> <p>14 BY MR. GORDON:</p> <p>15 Q. Yes, please. Can I direct your attention to page 1584?</p> <p>16 (Exhibit Reed 4 marked for identification.)</p> <p>17 Q. It is actually a full e-mail chain. The full e-mail</p> <p>18 chain goes from 1584 to 1589.</p> <p>19 A. Okay.</p> <p>20 Q. Got it? And the bottom half of that page, 1584, is that</p> <p>21 an e-mail from you to Mark Albrecht and Paul McGovern?</p> <p>22 A. Yes.</p> <p>23 Q. And is this -- it concerns what ultimately became the</p> <p>24 published McGovern paper; right?</p> <p>25 A. I would have to read that, but it sounds likely. Yes,</p>	<p style="text-align: right;">Page 123</p> <p>1 MICHAEL R. REED</p> <p>2 that would be right.</p> <p>3 Q. If you look at the second full paragraph under your</p> <p>4 comments, could you just read that one? It starts with</p> <p>5 "the infection reduction data".</p> <p>6 A. So I have said:</p> <p>7 "The infection reduction data has been given too</p> <p>8 much prominence. Whilst the data is real and can be</p> <p>9 used in the discussion, it is potentially controlled by</p> <p>10 many factors and I am not prepared to imply that this is</p> <p>11 solely a forced air warming effect. We have made lots</p> <p>12 of interventions -- it could be any, although I agree it</p> <p>13 could largely be a forced air warming effect."</p> <p>14 Q. By whom was the infection reduction data being given too</p> <p>15 much prominence?</p> <p>16 A. Well, I think I am referring to the first draft, which</p> <p>17 I think was done by Mark Albrecht.</p> <p>18 Q. And based on the e-mail at the top of that, after a --</p> <p>19 a week after you sent that e-mail about infection</p> <p>20 reduction data being given too much prominence, Albrecht</p> <p>21 sent back to you and Paul McGovern, with a carbon copy</p> <p>22 to Scott Augustine and Christopher Nachtsheim, what he</p> <p>23 describes as the first official rough draft of the</p> <p>24 paper. Do you know what that means?</p> <p>25 A. Well, it is a rough draft of the paper, yes.</p>
<p style="text-align: right;">Page 124</p> <p>1 MICHAEL R. REED</p> <p>2 Q. Was Mark Albrecht the primary writer of the paper?</p> <p>3 A. He had the first go at this paper and I think many other</p> <p>4 papers.</p> <p>5 Q. Do you know why Scott Augustine was copied on this?</p> <p>6 A. I think he was on the payroll at that time. Mark -- in</p> <p>7 fact, he's got an Augustine e-mail address.</p> <p>8 THE EXAMINER: So over the page at 1585, when he wrote to</p> <p>9 you on 22 December, saying:</p> <p>10 "I've started getting serious about getting your</p> <p>11 manuscript done."</p> <p>12 What does that mean, as you understood it?</p> <p>13 A. I think he was going to do a draft of the paper.</p> <p>14 THE EXAMINER: So he actually did the initial first draft?</p> <p>15 A. Yes; I am 90 percent sure he did that.</p> <p>16 THE EXAMINER: Okay.</p> <p>17 BY MR. GORDON:</p> <p>18 Q. If I could now move you to 1601 through 1607; another</p> <p>19 e-mail chain.</p> <p>20 It looks like this is a few days later than the one</p> <p>21 we just looked at. In particular, I want to draw your</p> <p>22 attention to page 1602, where you say -- at the top,</p> <p>23 where you say:</p> <p>24 "Mark, the paper reads well and (until the reviewers</p> <p>25 complain!) I am happy to include both the spinal data</p>	<p style="text-align: right;">Page 125</p> <p>1 MICHAEL R. REED</p> <p>2 and the infection plots. Could you have a read through</p> <p>3 and I would be very grateful if you could address</p> <p>4 comments and add references. I will also need a new</p> <p>5 deep infection chart drawing up and stats when I have up</p> <p>6 to date data. Same message but a couple of infections</p> <p>7 under CFW with many more numbers of primaries. It makes</p> <p>8 the data much more credible with the same message."</p> <p>9 What did you mean by that?</p> <p>10 A. Well, it's just a longer follow-up in the forced air</p> <p>11 warming group.</p> <p>12 Q. What was the reference to making it more credible?</p> <p>13 A. Well, the more patients you have in it, the more</p> <p>14 credible it is. I mean, that's what that ...</p> <p>15 THE EXAMINER: What does the sentence:</p> <p>16 "Same message but a couple of infections under CFW</p> <p>17 with many more numbers of primaries."</p> <p>18 What does that mean?</p> <p>19 A. It means we have had infections under forced air</p> <p>20 warming -- sorry, under conductive fabric warming. So</p> <p>21 I was more or less telling him that it wasn't going to</p> <p>22 be data that he would particularly love, but</p> <p>23 nevertheless it probably still shows an advantage. That</p> <p>24 was my view at that point. So we had had more</p> <p>25 infections.</p>

Page 126

MICHAEL R. REED

THE EXAMINER: As many more numbers of primaries?

A. So that means that the -- so essentially, "primaries" means the primary joint replacement. So we had done --

THE EXAMINER: Primary?

A. Primary joint replacement. So we had done lots of operations. We had two more infections. So that's -- compared to the data we had seen before, I think it's presumably saying ...

BY MR. GORDON:

Q. If you could turn to page 718 through 739.

THE EXAMINER: What is this, sorry?

MR. GORDON: I think that goes back to volume 2.

THE EXAMINER: 718?

MR. GORDON: 718 through 739.

A. Okay.

BY MR. GORDON:

Q. And on the cover page of 718, it shows as authors: Mike Reed, Mark Albrecht, Oliver Kimberger, Mark Litchy and David Leaper.

Do you know what this is?

A. So I think this is an early version of the -- of Reed et al, as you call it.

Q. The one that we find at page 505 through 510, are the authors Reed, Kimberger, McGovern and Albrecht?

Page 128

MICHAEL R. REED

Q. Okay. One more.

A. This paper was never published, as far as I am aware.

Q. Did you participate in writing it?

A. I don't think so.

Q. Are you even aware that -- strike that.

Was it the practice for somebody else to author something with your name on it and then ask you to sign on as an author?

A. No. I mean, the involvement, if you like, of the clinicians was to have a clinical context to the data. So in the paper that I eventually -- the Reed et al, you know, my involvement was really to put some -- add some weight to it, essentially, and that's the reason that I was on that.

I think my recollection of that particular paper was that it was pretty well written. I think that -- just let me get this clear in my ...

The Reed paper, I actually put quite a lot of time into. Is there a copy of that?

MR. HOLL-ALLEN: 505, I think we said.

THE EXAMINER: 505.

A. Was it in here as well?

MR. HOLL-ALLEN: Yes, it is in the same volume, 505. Ah no, sorry. That is the plaintiffs' bundle. You want

Page 127

MICHAEL R. REED

A. I think so. To be clear, I have not -- I think that probably -- yes, that will be this paper, sent in Vienna.

THE EXAMINER: So this is what you would call Reed 2013?

MR. GORDON: Yes.

BY MR. GORDON:

Q. So what was David Leaper's involvement in that paper?

A. So I don't know, is the truth of it. My recollection of this, when I was going through this last week, is that he was on early versions of this paper, but he wasn't on the final version.

Q. You don't know why?

A. I don't know why. He would be the best person to tell you. I can speculate, but that would be speculative.

THE EXAMINER: No.

BY MR. GORDON:

Q. Okay. If you could turn to pages 741 through 754. On page 741, it identifies authors of this paper as Leaper, Reed, Wim -- W-I-M -- Amsterdam and Mark Albrecht. Do you have any idea what this is?

A. I don't have any recollection of this, I am afraid.

I don't know whether I should, but ...

Q. Do you have any idea who "Wim" refers to?

A. No.

Page 129

MICHAEL R. REED

volume 2.

A. I think, isn't it in here as well?

MR. HOLL-ALLEN: It may be.

A. I was just going for an easier ...

So the forced air warming evaluation and intake filtration actually, I put quite a lot of work into, in terms of the paper, because it took quite a lot of understanding. I don't know if you read that paper. It is a complicated paper.

THE EXAMINER: That is why it is well written. I have not read it, because I was not given the task.

A. So I had quite a lot of input into that, albeit after the experiments were done. But the concept there of filters and the likes took quite a lot of understanding for me.

BY MR. GORDON:

Q. The experiments were done in Minnesota; right?

A. That one was done in, I think, Minnesota and in Vienna. So there were two aspects to that study.

Q. If I could have you turn to page 1479 now. It is an e-mail chain, 1479 to 1480. I want to ask you about --

MR. ASSAAD: On exhibit 3?

MR. GORDON: It is in exhibit 4, actually. Sorry.

Page 130

1 MICHAEL R. REED
 2 THE EXAMINER: 1479?
 3 MR. GORDON: Yes.
 4 BY MR. GORDON:
 5 Q. What I want to direct your attention to is the top of
 6 1479 and just really -- it doesn't show you as being
 7 copied on it, so I just really want to ask you if you
 8 are aware of any discussion about the line:
 9 "Ok, Scott, that leaves you with a decision to
 10 make."
 11 MR. ASSAAD: Objection.
 12 BY MR. GORDON:
 13 Q. "Pick 1 of 3 options.
 14 "1) We ask Mike Reed to take lead on this abstract
 15 also."
 16 MR. ASSAAD: I am going to make an objection before you
 17 enter it into the record. Something -- you failed to
 18 establish foundation. He is not even on the e-mail.
 19 You are just testifying here. This is not proper.
 20 MR. GORDON: Gabriel, are you going to be okay with me
 21 interrupting you in the middle of a question?
 22 THE EXAMINER: Carry on, Mr. Gordon.
 23 MR. ASSAAD: If I am reading an e-mail from somebody else,
 24 feel free.
 25 THE EXAMINER: He has ...

Page 132

1 MICHAEL R. REED
 2 A. No.
 3 THE EXAMINER: Were you asked to take the lead on this
 4 abstract?
 5 A. I am not entirely clear what this refers to, to be
 6 honest. It could be almost anything, in terms of
 7 papers. There's no attachment.
 8 THE EXAMINER: Well, it is. It is a forced air warming
 9 abstract document.
 10 A. Have we got that?
 11 THE EXAMINER: I don't know where the document ...
 12 MR. GORDON: Well, when I find it, I will circle back to
 13 this.
 14 THE EXAMINER: Okay.
 15 MR. GORDON: You see the crud and bug. Just put that into
 16 the back of your head. We will come back to that.
 17 BY MR. GORDON:
 18 Q. Since we are in this volume, I just want to deal with
 19 one small thing and get it done with.
 20 If you look at 1494 through 1505 -- correction, 1492
 21 through 1505.
 22 And at the beginning of this, there's an e-mail
 23 chain and then an attached draft of a presentation.
 24 Is this at all familiar to you?
 25 A. I mean, I have certainly read it in the last couple of

Page 131

1 MICHAEL R. REED
 2 MR. ASSAAD: He does not. He is not copied on it.
 3 THE EXAMINER: It does not matter.
 4 MR. ASSAAD: It does matter.
 5 THE EXAMINER: What rules ...
 6 MR. ASSAAD: The Federal Rules of Evidence.
 7 THE EXAMINER: All right. You make your objection.
 8 MR. ASSAAD: That is what I am doing.
 9 THE EXAMINER: Carry on.
 10 BY MR. GORDON:
 11 Q. I will go back. The line I am asking back:
 12 "Ok, Scott, that leaves you with a decision to make.
 13 Pick 1 of 3 options:
 14 "1) We ask Mike Reed to take lead on this abstract
 15 also (maybe preferred choice).
 16 "2) We ask Bob Gauthier to take lead on this.
 17 "3) You take the lead author role (I also like this
 18 option equally to #1)."
 19 Have you ever seen this before?
 20 A. No.
 21 Q. Were you privy to any discussions with Mark Albrecht or
 22 Scott Augustine about Scott Augustine deciding who was
 23 going to be asked to be --
 24 A. No.
 25 Q. -- an author of the paper?

Page 133

1 MICHAEL R. REED
 2 weeks; and I have probably read it at the time I was
 3 copied in. It is my e-mail address.
 4 Q. You know, I apologize. I lumped together in that, the
 5 e-mail and the attachment. The e-mail chain just goes
 6 from 1492 to 1498; and then 1500 to 1505 is the attached
 7 draft. That's what I'm talking ...
 8 Oh, I am sorry. Before we leave that e-mail chain.
 9 If you look at 1496, please. In the middle of the
 10 page, there is an e-mail from Mark Albrecht to
 11 Paul McGovern with a carbon copy to Mike Reed,
 12 Scott Augustine, Brent Augustine and "Nach001" and the
 13 text of that is:
 14 "Much better Paul. You did a good job of hiding the
 15 'agenda' and making this look much more impartial. I'll
 16 give you an updated infection graph and summary
 17 tomorrow."
 18 What was your understanding of what "agenda" Mark
 19 was praising Paul for doing a good job of hiding?
 20 MR. ASSAAD: Objection. Calls for speculation.
 21 THE EXAMINER: Did you have an understanding?
 22 A. I can speculate, I can speculate on it.
 23 THE EXAMINER: No.
 24 A. I mean, I wasn't --
 25 MR. ASSAAD: We don't want you to speculate.

Page 134

MICHAEL R. REED

A. -- engaging in that conversation, so I would be speculating.

BY MR. GORDON:

Q. So as you sit here today, you don't remember any discussion of an agenda that you wanted to hide, with this presentation that you and Dr. McGovern gave?

A. No, I don't think -- I am speculating, but I don't think the agenda is referring to Paul McGovern.

Q. Okay. One other question before we leave the e-mails. At the very bottom of 1496, Brent Augustine sends an e-mail to Mark, CCed to others, but he specifically says:

"Dr. Reed, it was nice to see you in San Diego. The research was extremely well received by those that saw it."

Do you know what that was referring to?

A. Just let me check the date. So -- sorry, which page are you on?

Q. 1496.

A. So -- well, I mean, I had been to San Diego once. It was for the American Academy of Orthopaedic Surgeons. It must have been there. Did I present there? Probably.

Q. Do you recall what you presented?

Page 135

MICHAEL R. REED

A. No. I could find out, probably. As far as I am aware, it wasn't on anything related to this.

Q. Okay. That was going to be my question.

Did you ever speak at a conference on anything related to forced air warming where Scott Augustine or his company helped you with travel costs or lodging costs?

A. Me? No.

Q. Someone else?

A. Well, Paul McGovern, I think, went to Minneapolis and my recollection was that I advised him to get receipts and just get them reimbursed and not to take anything financial. That's my recollection of it.

Q. Okay.

Now, I want to flip to 1500 through 1505. It is titled "Outline of BHS presentation". And if you look at the comment boxes on the right, on that first page, 1500, the very first comment is:

"Comment: MRR1."

A. Mm-hm.

Q. Who is MRR1?

A. Very likely to be me, I would say.

Q. And you -- this outline indicates that the presenters of this BHS presentation are Paul McGovern and Mike Reed.

Page 136

MICHAEL R. REED

Was there ever such a presentation?

A. Yes. So I think this is a presentation at the Hip Society, which was in Bournemouth or the south of England somewhere, in about -- well, it was the meeting in probably 2011, 2012, something like that. It was the same meeting that we got declined the other -- the original piece of research we did. That was declined at this meeting. This one was accepted.

Q. Okay.

This presentation doesn't reference that negative microbiology study, does it?

A. Correct, that was declined. So the two separate -- I mean, he may well have put lots of papers in. I think at that particular meeting, I personally and my team had loads and loads of papers in. That -- so the first one wasn't accepted. This one was accepted. So he gave this presentation.

Q. If you drop down to the bottom comment on page 1500, "M3". First of all, do you know who the "M" comments are coming from?

A. I am speculating, but it's probably Mark --

MR. ASSAAD: Objection.

A. Well, I don't know, no, is the answer.

THE EXAMINER: I don't quite understand these commented

Page 137

MICHAEL R. REED

boxes. "MRR1", you say, is you?

A. I think it is my first comment.

THE EXAMINER: But "M2", which continues the sequence, is obviously from someone else, because it says "I agree with Mike".

A. Yes.

MS. ZIMMERMAN: Just the ...

THE EXAMINER: No, I don't think it is M1, because it is that person's first comment.

MR. GORDON: There might have been an M1 that, you know, he deleted before it got sent.

MR. ASSAAD: No, because there is MR5 after M4.

MR. GORDON: I have seen, I ...

THE EXAMINER: I saw this the other day and I was very confused by it.

BY MR. GORDON:

Q. Looking at comment "M3" where it says:

"I suggest you add this as an additional slide to focus the direction of where you are going in the broader context, that you are only looking at one potential factor among many possible ['many' or 'may possible'] culprits. This makes it look impartial and hides our agenda, so to speak..."

MR. ASSAAD: Objection, hearsay.

Page 138

1 MICHAEL R. REED
 2 BY MR. GORDON:
 3 Q. Do you recall any discussion with Mr. Albrecht about the
 4 need to make this presentation that you were and
 5 Dr. McGovern about to give --
 6 MR. ASSAAD: Objection. Sorry.
 7 MR. GORDON: Gabriel, let me finish.
 8 MR. ASSAAD: I thought you were done. You had a question --
 9 THE EXAMINER: Okay, let him finish.
 10 MR. ASSAAD: I thought he had finished.
 11 A. Just to be clear, that is not my comment, M3.
 12 BY MR. GORDON:
 13 Q. I understand, I understand. I am just wondering: when
 14 you saw the back and forth on these comments, did you
 15 even read that one?
 16 A. I probably haven't -- I mean, I have probably read this
 17 once and commented. And he's made comments after I've
 18 read it, because I don't -- well, is there any of his
 19 things that I have commented on? I suspect he's
 20 commented after me.
 21 MR. ASSAAD: I would like to make an objection to the last
 22 question. It assumes facts not in evidence. You said
 23 this was Albrecht's comment and that has not been
 24 established.
 25 MR. GORDON: That is what Mr. Albrecht testified to, so

Page 139

1 MICHAEL R. REED
 2 I consider that a fact established in evidence already.
 3 MR. ASSAAD: That is not --
 4 MR. HOLL-ALLEN: May I intervene to say this. Mr. Gordon
 5 said a moment ago to the witness:
 6 "When you saw the back and forth in relation to
 7 these comments."
 8 With respect, I don't know whether it has been
 9 established that at the time, Mr. Reed saw the back and
 10 forth in relation to these comments; in the sense that
 11 it seems to me to be perfectly plausible that he made
 12 comments, and then M made comments which he did not
 13 subsequently see.
 14 So it seems to me that there has to be a better
 15 foundation for the questions, and an assumption is being
 16 made about a factual issue which has not been accepted.
 17 THE EXAMINER: So we would have to see an MRR response to
 18 an M comment.
 19 MR. HOLL-ALLEN: I think we would, or the witness would have
 20 to accept that he had seen the M comments at the time;
 21 and I don't believe that he has accepted that.
 22 BY MR. GORDON:
 23 Q. If you turn to page 1501. At the very bottom, there is
 24 a comment, MRR8:
 25 "Are there any pictures of this in use with models?"

Page 140

1 MICHAEL R. REED
 2 Ideally an attractive one."
 3 Comment, M9:
 4 "I know the exact picture Mike wants ... I'll get it
 5 to you."
 6 Comment, MRR10:
 7 "Need to mention the improved efficiency. Watts
 8 spend etc. Mark will have figures in comparison to
 9 FAW."
 10 Does that refresh your recollection as to whether
 11 you only made comments once and did not review any
 12 responsive comments?
 13 THE EXAMINER: No, I am sorry, Mr. Gordon. That does not
 14 work.
 15 A. No, I don't think so. No, that is a separate --
 16 THE EXAMINER: If you look at the dotted line, it is clear
 17 that M9 responds to MRR8, but MRR10 is a separate
 18 comment. It is not responsive to M9.
 19 MR. GORDON: Right. But it is sequentially current.
 20 THE EXAMINER: Well, that is -- it is in the document.
 21 MR. GORDON: It is not sequentially referring to his first
 22 comment. Comment MRR10 does not respond sequentially to
 23 MRR8. In other words, they weren't done at the same
 24 time. I am not going to belabor the point. It is --
 25 THE EXAMINER: They may have been done a minute later,

Page 141

1 MICHAEL R. REED
 2 I don't know, but ...
 3 A. I think the way track changes works is to -- they have
 4 all got different numbers. Every comment has got
 5 a different number. That doesn't mean that I have
 6 seen -- there is nothing in here that makes me think
 7 I have seen the conversation. I have seen it once,
 8 I suspect. It would be unlikely that I would do it
 9 twice, to be honest.
 10 BY MR. GORDON:
 11 Q. So when you commented, MRR6:
 12 "I'm tempted to say the driver for this was the need
 13 to verify the smoke DVD produced by Augustine ... remind
 14 them that this DVD was posted to all orthosurgeons in
 15 U.K. last year (assuming that is correct)."
 16 So the comment, M7:
 17 "I'd be careful here. That might imply a strong
 18 corporate agenda behind these activities and raise
 19 questions as to the credibility of the results."
 20 You never saw that response?
 21 A. I don't think so. I mean, I couldn't honestly say I saw
 22 it. It would be unlikely that I would review a trainee
 23 presentation twice, before going. But it's possible
 24 I did.
 25 Q. Okay.

MICHAEL R. REED

If you turn to the final page. I'm sorry, 1505. It is your comment, MRR20, I want to ask you about. It is -- at the bottom, there's somebody saying:

"Notes -- for discussion, or to fit into main body."

And one of them is:

"Mention infection data from Northumbria."

And the dash line goes over to your comment, MRR20:

"Suggest you hold this as the very last slide -- one that is placed after your thank you slide at the end.

If you are lucky you can steer a question into exposing it. Normally work a treat and can be introduced with 'I thought you might ask that...'"

What did you mean by that?

A. So when you give your presentation, you have essentially being accepted to give a presentation on a particular topic. And that was on the -- from my recollection, that was on the difference between forced air warming and conductive fabric warming that we did on the experimental -- on the experimental sort of one in theater.

But a common question after that sort of thing is: how does this apply to clinical practice? That would be the next question.

So you can't really present on it in your main

MICHAEL R. REED

presentation, because that's not what they have given you permission to do. But if then someone in the audience asks, that's when you can show, you know, a relevant slide.

And that's something that I will do fairly routinely, is to try and anticipate a question that I think will be -- that will be asked, and then you can answer it. Rather than with a sort of a bumbling statement, you can actually have something to show.

THE EXAMINER: So the slide is on the screen?

A. Yes.

THE EXAMINER: And you are hoping that someone is going to say: "I want to ask questions about that"?

A. Yes and I might hold two or three slides that I might get asked and so my thank you slide is up and someone asks me. I say: "Well, I thought you might ask. I have got a slide on that." And just -- it is a fairly common practice.

BY MR. GORDON:

Q. Why didn't you want to have the issue of the infection data presented during the --

A. Because the abstract that had been accepted was not a clinical paper. It was a specific experiment. That's what the -- you know, if they accept that, you can't

MICHAEL R. REED

really go with something else. You need to go with what they have accepted and present that. It would be -- because otherwise you could just turn up with anything and say anything in your slot.

Q. Had you submitted the infection data part of the study?

A. I think that was too early at that point. That was, I think -- I forget when this was, but this was probably 2010. So there might have been a hint towards some data at that point.

Q. Okay.

If you turn now to the e-mail chain, 1529 through 1535. The top page, 1529, is an August 20, 2010 e-mail from Mark Albrecht to you and Paul McGovern, with a CC to Nachtsheim, Gauthier and Scott Augustine.

Do you recall seeing this before?

A. I saw it the other day, but I am sure I did receive it at the time.

Q. Yes.

At the bottom, he says that:

"Bob is more than happy to assume the lead authorship role and verify the fidelity of our research (he has seen it first hand). Further, I'm sure Chris will also vouch for that since we brought him over to take a look at it too. If we take the burden off of

MICHAEL R. REED

both of you as being lead authors, would you be comfortable with submitting the current publication as is with a role as secondary authors? The only reason I ask is that I've got a backlog of these things to get in that are just sitting here -- without any clue as to when the bubble generator will clear customs. I'd like to target anesthesiology journal with this article anyways, so Bob is a natural choice for lead author."

What does that refer to?

A. So --

MR. ASSAAD: Objection, calls for speculation.

A. I am just trying to think about the timeline, 2010.

That -- I am speculating, and I know that's not allowed, but ...

THE EXAMINER: No, thank you.

A. Okay, fine.

THE EXAMINER: See if you can reword the question, Mr. Gordon.

BY MR. GORDON:

Q. Okay.

Was there -- we have probably talked about this earlier -- some study that had been done in Minnesota that you didn't actually see?

A. The Belani study, yes.

Page 146

MICHAEL R. REED

Q. Okay, so that refers to the Belani study. And the co-authors on that were Albrecht, McGovern, you and Nachtsheim; right?

A. Yes.

MS. ZIMMERMAN: And that binder is going behind tab 4.

A. Yes.

Do you want me to comment or ...?

BY MR. GORDON:

Q. Go ahead.

A. I am not sure, in honesty, whether this e-mail refers to this paper. I don't know how you have linked that. It may be so. If you could help me out, that would be good.

Q. No. I know that I can't help you any more than that. If you don't know, you don't know.

But if you turn to page 1532 in the e-mail chain -- no, in that one. There appears, at the top, an e-mail from Robert Gauthier to Mark Albrecht, Mike Reed, Paul McGovern, CCed to Nachtsheim, Gauthier and Scott Augustine. It says:

"Mike and Paul. As Mark mentioned, I have worked closely with these guys."

I am not going to read the whole thing, but do you recall seeing that?

Page 147

MICHAEL R. REED

A. Well, I recall reading the whole transcript yesterday, which was interesting.

Q. What was interesting about it?

A. Well, it looked as if the e-mail text had been authored by my recollection and here was -- by Albrecht, or by somebody else.

Q. In your experience, was that unusual for Mr. Albrecht to ghost write, if you will, communications on behalf of other people?

A. I never saw him write any communications. Well, obviously -- I mean, I have just seen this now and that was to me; so it obviously happened. But I wouldn't be aware of that happening, no.

Q. Was there ever a time he drafted a letter to the editor for your signature, concerning criticisms of flaws in the McGovern study?

A. Yes. So I mean, like the papers, he would tend to do the first draft and he did draft a letter which actually, I think ultimately I didn't send. But he did draft a letter.

THE EXAMINER: And that was criticizing ...?

A. My recollection is that it was a letter commenting on a paper criticizing my paper.

THE EXAMINER: Right.

Page 148

MICHAEL R. REED

A. I think.

BY MR. GORDON:

Q. Why did you decide not to send it?

A. I think there was a couple of reasons.

One initially was that I was concerned that it was double publishing the same data, which is kind of frowned upon. That was my main concern.

As time went on, there was more data I could have put in it and a sort of extended follow-up, but it was a particularly busy time of year.

In fact, I was doing a lecture tour in the States that summer and by the time I came back, that was never being pushed. I don't know if Albrecht was no longer working for Augustine or something had happened, but I was pushed -- not pushed, but I was reminded constantly to do it, and then the reminding stopped and I never got round to it.

Q. I am going to flip to the e-mail chain that goes from 1519 to 1522.

And at the bottom of the first page, 1519, there is an e-mail from you to Mark Albrecht with a CC to McGovern, Nachtsheim, Scott Augustine -- two S. Augustines -- T. Neils. You go on:

"Thanks Mark, very impressive. The transfusion data

Page 149

MICHAEL R. REED

is unreliable, I'm afraid -- it just shows errors we are making in coding/billing. It is actually about 10 percent. I can get the reliable data but it would take quite a lot of work. Likewise I can get ASA grade but possibly BMI by pulling the charts/notes. I suggest we don't do that as I don't have the resource -- what do others feel?"

What are you referring to there?

A. So do you remember, we started today with that big long spreadsheet that has codes collected by professional coders on what happened to the patient? So you can reliably get data on whether they either had a heart attack or whether they had a chest infection. But we know that the transfusion box on that, even though we collect the data, we know it's unreliable.

So the best way of getting that data is to go to the transfusion lab and cross reference with their data. So I could get it, but actually it would be quite a lot of work and insofar as our paper was concerned, not of much relevance.

So that is the transfusion data.

Likewise, for ASA grades, anyone know what the ASA is?

Q. Why don't you explain what that is?

Page 150

MICHAEL R. REED

A. So the American Society of Anesthesiologists. It is their grading system, which essentially is a grading system to see how healthy you are. So ASA grade 1 is very healthy and ASA grade 5 is very unhealthy. So we do have that data. It is collected, but it is not collected electronically. So I would have to go back to each patient's notes, which would be several hundred sets of notes.

THE EXAMINER: It would be a massive job.

A. A massive job. So for the value it was going to give us ...

So I suggested, I think, perhaps in this conversation, that we do something called Charlson scoring.

BY MR. GORDON:

Q. If you turn to 1521 at the bottom.

THE EXAMINER: How is it this gentleman can print out these e-mails running in date order, as opposed to reverse date order?

(Off the record remarks.)

BY MR. GORDON:

Q. "Mark, I agree hypo and hyperthyroidism and COPD would be useful but only if the list was more complete. I think it would highlight the fact that we don't have

Page 151

MICHAEL R. REED

ASA data, obesity and transfusion. We should leave out."

Why -- what is the reference there to highlighting the fact that: "We don't have ASA data, obesity and transfusion"?

A. Well, if we did not have it in the dataset, we would have to go and look for it. So it would be a big piece of work, so I was not keen to embark on that. You might embark on that if the reviewers really wanted it. If they are saying: "We will publish your paper if you get that", then it would be worth pulling 1,000 sets of notes or whatever.

But for the benefit, it probably wasn't worth it.

Now, what I have suggested is that we did have robust data on those three things; hypo, hyperthyroidism and COPD. But in itself, if you put that in, people would say: "Why are you collecting that and not other things that are more obviously linked, like ASA, obesity and transfusion?" So it would just alert the reviewers to the fact that we haven't got that data.

Q. I recognize that it was a whimsical statement, but what did you mean by:

"It is fair to say my assassin may be funded by Bayer or Arizant!"

Page 152

MICHAEL R. REED

A. Because both of those companies -- so Bayer make rivaroxaban. Well, we know what Arizant made. So you know, it was clear to me that they wouldn't like what I was saying.

Q. Okay. Maybe I do need to be more specific. What was the concern with respect to Bayer?

A. Because we published our paper on rivaroxaban. Do you remember, the one we discussed at length earlier, about --

Q. Okay.

A. -- the return to theater rates?

THE EXAMINER: That was the --

MR. GORDON: Separately.

THE EXAMINER: That was the short period for which you used it.

A. Yes. And also we wrote a paper about ten other hospitals, which we have not discussed today, I think it is in the package, showing the same effect. So --

THE EXAMINER: What is Charlson scoring?

A. So the Charlson score is a predictor of likelihood to die, essentially. So it looks at a variety of measures like: have you got heart disease, have you got lung disease, have you got HIV? All of these things. And it produces a scoring system for your chance of dying. So

Page 153

MICHAEL R. REED

it is useful -- if your paper is, for instance, on mortality, then it is useful to be able to grade the patient's Charlson score, so you can compare big groups of patients.

And we can do that from the spreadsheet, you know, that exhaustive spreadsheet we had before. I can turn that into a Charlson score for any individual patient, so you risk assess them.

BY MR. GORDON:

Q. Do you currently use the Hot Dog?

A. No, I don't, actually.

Q. When did you stop using the Hot Dog?

A. In -- certainly earlier on this year.

Q. What do you use now?

A. So we are currently undergoing an evaluation of different systems.

So in the last six months -- well, certainly this year, I have used the Hot Dog. But we had some difficulties with them beginning to bubble and sort of melt; "melt" is an overexaggeration, but they began to bubble along the seams and we were anxious that the patient was going to get injured. So we stopped using them, we pulled them.

And we are currently trialing different conductive

Page 154

1 MICHAEL R. REED
 2 fabric systems, different companies; and sometimes used
 3 forced air warming if there was nothing else available.
 4 Q. Which forced air warming system do you use, if there is
 5 nothing else available?
 6 A. Bair Hugger.
 7 Q. Have you yourself used Bair Hugger in the last six
 8 months?
 9 A. Yes.
 10 Q. How about the other surgeons at Northumbria? Have any
 11 of them used Bair Hugger in the last six months?
 12 THE EXAMINER: Do you know --
 13 A. Yes.
 14 THE EXAMINER: -- what other surgeons use?
 15 A. They will have used Bair Hugger and they will have used
 16 conductive fabric, because we are doing -- we are sort
 17 of evaluating different systems and we haven't always
 18 got conductive fabric available. So yes. There are
 19 some surgeons I know who are refusing to use
 20 Bair Hugger, but I am not one of them.
 21 BY MR. GORDON:
 22 Q. I think we need to go back to volume 1, which is
 23 exhibit 1.
 24 (Off the record remarks.)
 25 Q. Mr. Dyer, I think you might have my volume 1.

Page 156

1 MICHAEL R. REED
 2 is page 371.
 3 THE EXAMINER: Yes, but what is the internal Albrecht
 4 reference?
 5 MR. GORDON: I am sorry?
 6 THE EXAMINER: What is the internal Albrecht reference? The
 7 Bates stamp?
 8 MR. GORDON: Oh, 0018360.
 9 Did you not have a paginated one? Because there is
 10 another ...
 11 THE EXAMINER: Oh, there is one here.
 12 MR. GORDON: That is all I am using.
 13 THE EXAMINER: So page number now, 3 ...
 14 MS. OKONEDO: 371.
 15 THE EXAMINER: Thank you.
 16 MR. GORDON: Page 371.
 17 A. Ah, 371.
 18 BY MR. GORDON:
 19 Q. Yes, yes. Sorry.
 20 A. Oh, sorry.
 21 THE EXAMINER: This is a back to front order.
 22 MR. GORDON: Sorry?
 23 THE EXAMINER: This is a back to front order.
 24 BY MR. GORDON:
 25 Q. It is an exchange of e-mails with you and Scott

Page 155

1 MICHAEL R. REED
 2 THE EXAMINER: Volume 1?
 3 MR. GORDON: Yes. Is there an extra volume 1 over there?
 4 MR. ASSAAD: Mr. Videographer, what is the current time?
 5 The current time, for the record?
 6 THE VIDEOGRAPHER: We have been on the record for three
 7 hours and 21 minutes.
 8 MR. ASSAAD: Thank you.
 9 MR. GORDON: How much of that time was Mr. Assaad spending
 10 making his speaking objections? You don't have to
 11 answer that.
 12 MR. HOLL-ALLEN: Does anyone want this folder, volume 1?
 13 THE EXAMINER: If someone can tell me which tab and which
 14 internal Bates stamp, I am perfectly happy.
 15 MR. GORDON: I am actually winding up pretty quickly, but
 16 I guess I didn't understand the order to say three and
 17 a half hours, regardless of how much time the plaintiffs
 18 consume with --
 19 THE EXAMINER: Three and a half hours is what you get. I do
 20 not notice that there have been an excess of
 21 interventions which would have -- in that time. Believe
 22 me, I have heard much longer interventions, with much
 23 more frequency.
 24 Which tab are we going to?
 25 MR. GORDON: I will start with -- it is under tab 5, but it

Page 157

1 MICHAEL R. REED
 2 Augustine and Brent Augustine, Paul McGovern. It is
 3 really just one line I want to ask you about, at the
 4 very bottom. You said:
 5 "I don't have a great appetite for writing to the
 6 editor, though. I think there is probably enough
 7 background concern, so it is reaching people's
 8 consciousness. What we need here is an RCT."
 9 First of all, do you know what letter to the editor
 10 that refers to?
 11 A. I think it's probably the letter which we discussed ten
 12 minutes ago, that Mark Albrecht had started and drafted.
 13 Q. What did you mean by: "There is probably enough
 14 background concern, so it is reaching people's
 15 consciousness"?
 16 A. I think people were talking about it. People --
 17 Q. What is "it"? What were people talking about?
 18 A. I think people accept that it affects laminar flow.
 19 I think it is much more contentious, whether it affects
 20 infection rates. I think it is pretty accepted that
 21 forced air warming will affect your laminar flow,
 22 because of the way it affects air movements and the
 23 heat. It is very fragile.
 24 Q. And then the last line:
 25 "What we need here is an RCT."

Page 158

MICHAEL R. REED

What is that a reference to?

A. So this goes back to the thing I have been saying since 2009. We had a randomized control trial. We needed a big trial to show if there is a difference between forced air warming and conductive fabric warming, in terms of infection rates.

Q. Are you aware of any such trial, either underway or planned?

A. So there is a planned trial, which I am a principal investigator for, which means that I am not leading it; but I am, if you like, on the grant and I am on the team that are hopefully going to run the trial.

Q. How were you recruited to be part of that?

A. So the chief investigator has, I think, probably seen me show the videos of how it disrupts laminar flow or something similar, at least. He -- he is not an orthopaedic surgeon. He is an infectious disease consultant.

Q. That is Professor Scarborough?

A. Yes, I think so.

THE EXAMINER: Professor?

A. Scarborough. Dr., I think.

BY MR. GORDON:

Q. Scarborough. I am sorry. He asked you to be part of

Page 159

MICHAEL R. REED

the research team?

A. I think -- I can't remember. Well, I suppose he did, because I haven't led it. He has come to me. I would be a reasonably natural person to come to, because we do a lot of randomized trials and I have clearly got an interest in this.

Q. And what is the randomized trial going to be comparing?

A. So it's a pilot study, which means it is a study where we are trying to gain information to see what we would have to do for a big trial. But it's randomizing patients with a hip fracture, who are having a hemiarthroplasty with a very high rate of infection. So if you break your hip in your 70s and 80s, then you have a much higher rate of infection. So we've chosen that group deliberately. Because of the high infection rate, you need smaller numbers.

THE EXAMINER: That is in trauma situations specifically?

A. In trauma.

BY MR. GORDON:

Q. What is the intervention that you're going to be examining?

A. Conductive fabric warming versus forced air warming.

Q. And the end point is?

A. Infection.

Page 160

MICHAEL R. REED

Q. So when you talked about an RCT, is that --

A. That is the Holy Grail.

Q. That is the Holy Grail. Who is funding this?

A. 3M. Well actually, 3M and a charity. But 3M are certainly funding the pilot.

THE EXAMINER: A U.S. charity or a U.K. charity?

A. Are we ...?

THE EXAMINER: A U.S. charity or a U.K. charity?

A. Oh, a U.K. charity. It is something like the Infection Prevention Society or something like that. It is on my CV somewhere.

BY MR. GORDON:

Q. And this study that 3M is funding, that's similar to what you had wanted to do earlier and Augustine declined to fund; is that right?

A. Yes.

MR. GORDON: Thank you. I have nothing further.

THE EXAMINER: Right. Let's go off the record briefly.

THE VIDEOGRAPHER: Going off the record at 4:06.
(4:07 p.m.)

(Break taken.)

(4:17 p.m.)

THE VIDEOGRAPHER: Back on the record at 4:17.

EXAMINATION BY MR. ASSAAD:

Page 161

MICHAEL R. REED

Q. Mr. Reed, my name is Gabriel Assaad and I am one of the attorneys that represent hundreds of plaintiffs in the United States litigation with respect to Bair Hugger.

We have never met before; correct?

A. Correct.

Q. Have you met any attorneys that are representing plaintiffs in the United States with respect to this litigation?

A. I am not sure I understand the wording, but I haven't met any attorneys from the United States if that makes it easy.

Q. Have you met any attorneys that are representing the plaintiffs or the claimants with respect to this litigation?

A. No.

Q. Have you met with any attorneys that are representing 3M or Arizant with respect to this litigation?

THE EXAMINER: Before today?

BY MR. ASSAAD:

Q. Before today.

A. No.

Q. Have you been in contact with anyone from 3M regarding this litigation?

A. So I do randomized trials; that is one of the things

Page 162

MICHAEL R. REED

I do. And I am doing a randomized trial on a 3M product, which is completely unrelated to this. And they did contact me six months ago, essentially just agreeing that this was -- they were nothing to do with each other. And -- but it clearly was on their radar that this was going on. But apart from that, they wanted to hire me to do one of their studies on something completely different.

Q. And that would be the Crebbs(?); is that correct?

A. Yes.

Q. During those conversations or those meetings with 3M, did you have any substantive conversations about your viewpoint regarding this litigation or the substantive parts of this litigation?

MR. GORDON: Object to the form of the question.

THE EXAMINER: You may answer.

A. No, I don't think I did.

BY MR. ASSAAD:

Q. Now, before we get into the substance -- I am going to start off with the background, but I just want to go over a few ground rules, just so we are clear.

I am going to ask you numerous questions. If you do not understand my question, please let me know. Fair enough?

Page 163

MICHAEL R. REED

A. Yes.

Q. If you answer the question, we will assume that you understood the question I asked; fair?

A. Okay.

Q. And any time you want to take a break, please let me know. This is not an endurance contest, so please speak up.

And I'd ask you, as you have heard before, please do not speculate or guess to any questions. If you don't know the answer, it is okay to say "I do not know"; fair?

A. Okay.

Q. And also try to be verbal with a "yes" or "no", so the court reporter can take a clear record. So she can't take down you nodding your head; okay?

A. Okay.

THE EXAMINER: And if it is possible, because Mr. Gordon may want to put an objection on the record, pause for a moment before you start your answer to the question. I know it is very difficult.

A. Okay.

BY MR. ASSAAD:

Q. I would like to mark this as exhibit number 7, please.

THE EXAMINER: This is?

Page 164

MICHAEL R. REED

MR. ASSAAD: The CV.

(Exhibit Reed 7 marked for identification)

BY MR. ASSAAD:

Q. Mr. Reed, can you please describe what has been marked as exhibit number 7?

A. It is my curriculum vitae.

Q. Why was this prepared?

A. About two weeks ago.

Q. And it is dated November 21st, 2016. Is that when it was prepared?

A. Yes. That feels about right.

Q. Is this the most up to date version of your CV?

A. Yes.

Q. Is there anything in this CV that is not included, with regard to your education, training, background, employment?

A. I don't think there is anything major excluded that I am aware of. Everything big, I have put in.

THE EXAMINER: Was it prepared in response to the order in this case, or do you have one which you keep running all the time?

A. Yes, I have one that I update when needed.

BY MR. ASSAAD:

Q. On page 2, it has an index of your publications. Do you

Page 165

MICHAEL R. REED

see that?

A. Yes.

Q. And unfortunately, as I've got a PDF copy, I could not click here. Where is the link going? Is it going to PubMed?

A. Google Scholar.

Q. Google Scholar, okay.

And I, in fact, printed off a copy of the Google Scholar and I have approximately 214 publications that you have been part of; does that sound correct?

A. In terms of Google Scholar, yes, probably.

Q. Are there more than 214?

A. No. But Google Scholar is very inclusive. So there will be abstracts. So for instance, if you present at a meeting, like the Hip Society one, then it may well get onto Google Scholar when it wouldn't get onto PubMed.

Q. Okay. So they might not all be peer reviewed articles?

A. Yes.

THE EXAMINER: I am a little lost. PubMed?

A. So PubMed -- so PubMed is a website where you can look for papers that have been peer reviewed, if you like; so they are in a journal and they are peer reviewed. Whereas Google Scholar has a wider net and they will

Page 166

1 MICHAEL R. REED
2 pick up maybe so-called abstracts from meetings, so just
3 short pieces of work that are not necessarily peer
4 reviewed.
5 THE EXAMINER: So Google Scholar is produced as a result of
6 searches by someone else?
7 A. Yes, by --
8 THE EXAMINER: PubMed, do you post information to it, or is
9 there some sort of search?
10 A. So I think Google Scholar searches the whole internet
11 for your name. PubMed will only go to journals that are
12 peer reviewed and search their databases.
13 THE EXAMINER: Fine, thank you.
14 A. So probably I have 130, 140 on PubMed, I would think.
15 BY MR. ASSAAD:
16 Q. And according to Google Scholar, it is my understanding
17 that your peer reviewed articles have been cited over
18 2,700 times; does that sound about right?
19 A. I have never looked, but it does tell you. So that's --
20 you are probably right.
21 Q. Now, I just want to go briefly to your educational
22 background.
23 If you could start from the beginning, just so we
24 have a clear picture of -- a chronological picture of
25 your background, starting with your education, through

Page 167

1 MICHAEL R. REED
2 your training, through your employment.
3 So let's start with your education. Could you just
4 go briefly through your education?
5 THE EXAMINER: Which level; starting at which level?
6 BY MR. ASSAAD:
7 Q. The level right after what we would call high school.
8 A. Okay.
9 THE EXAMINER: From 18?
10 MR. ASSAAD: Yes.
11 THE EXAMINER: From 18 on.
12 A. Right. So I went to Newcastle University to do
13 medicine. They give you two degrees for that in our
14 country, MBBS. And then I did some training, further
15 training in the North East.
16 BY MR. ASSAAD:
17 Q. I don't mean to interrupt you. Could you just provide
18 dates, so we have a chronological picture of when you
19 started your training and finished?
20 A. Right, okay. I have got my CV, so this helps. In 1992
21 I started training, having qualified as a doctor. And
22 then I, two years later --
23 THE EXAMINER: Training as a surgeon?
24 A. Yes, training as a surgeon. But the first few years is
25 quite general.

Page 168

1 MICHAEL R. REED
2 And then I sat my first surgical exams in 1994.
3 I did the second part of my surgical exams in 1996.
4 I then joined a specialist training scheme in trauma
5 and orthopaedics, having first completed two years of
6 orthopaedic research in Sheffield. So I did six -- in
7 fact, five years on the training scheme in trauma and
8 orthopaedics in the North East.
9 Then I went on a fellowship to New Zealand and did
10 a specialist joint replacement and revision and
11 infection fellowship; and then did some trauma training
12 in New Zealand as well on a fellowship.
13 And then just before I went to New Zealand, I sat my
14 sort of consultant exams, I would say; maybe the
15 equivalent of your boards, in 2002.
16 And then I have been a consultant since 2002. It
17 looks like I was awarded a fellowship of the English
18 College of Surgeons without examination a couple
19 of years ago. So you -- in your early career, you tend
20 to have to sit an exam to get in. And then later on, if
21 they like you, then they will let you into a different
22 college without having to sit the exam. So that's what
23 that is.
24 BY MR. ASSAAD:
25 Q. Okay. And so FRCS is the equivalent of maybe the U.S.

Page 169

1 MICHAEL R. REED
2 boards; correct?
3 A. I would say FRCS trauma and orthopaedics is equivalent
4 to the U.S. boards.
5 Q. Okay.
6 A. So FRCS part 1 and 2 are maybe more junior surgeons. It
7 takes a very long time in the U.K. to train as
8 an orthopaedic surgeon, compared to the U.S.
9 Q. And to take your FRCS exam for trauma and orthopaedics,
10 do you have to have a certain qualification like so many
11 surgeries or so much experience?
12 A. Yes, you do.
13 Q. Can you please describe to the ladies and gentlemen of
14 the jury and the judge what qualifications and
15 experience is required to sit for the FRCS for trauma
16 and orthopaedics?
17 A. Right. So the -- there are rules around that, which are
18 soft rules. But to finish as an orthopaedic surgeon,
19 you have to have your trauma and orthopaedic FRCS exam
20 and then you have to have done so many types of surgery.
21 So you need to have had so many cases in your logbook,
22 et cetera, et cetera.
23 So actually, when I went through, it was not as
24 regulated. It is now very regulated.
25 Q. Right. And then you have -- I think you have mentioned

Page 170

MICHAEL R. REED

it, but FRCS England awarded ad eundem, in England. Is that without an exam?

A. Yes.

Q. And is that a special recognition when you get admitted or get qualified for FRCS England without an exam?

A. I -- in a way, I would say it was. That was how it was sold to me.

THE EXAMINER: So these previous --

A. They still make you pay.

THE EXAMINER: These previous FRCSs, were they not English?

A. So they are the College of Surgeons of Edinburgh. So there are several surgical colleges, all of which you can join; they are all of equal ranks, so --

THE EXAMINER: So you were Scots qualified until 2014?

A. Yes, and I am still Scots qualified. I am now doubly, if you like, if you want to call it a qualification.

BY MR. ASSAAD:

Q. For us that are not around here: what does that mean, "Scots qualified", as ...?

THE EXAMINER: Edinburgh.

A. So we have -- there are several colleges of surgeons. So there is the College of Surgeons of Ireland, one of Edinburgh, one of England, and I think the Glasgow one is physicians and surgeons. It is quite confusing.

Page 171

MICHAEL R. REED

But you have to be -- by law, you have to be a fellow of one of them, in order to -- because it is by exam and you have to pass your exam. And all the exams are actually the same exam. They have all joined up and do the same exam. And then you just -- one college will hold your -- take your money, essentially.

BY MR. ASSAAD

Q. It doesn't limit where you can practice; correct?

A. Correct. I mean, trauma and orthopaedics is where I practice. But yes, I can operate right across the breadth of trauma and orthopaedics, based on that qualification.

Q. I meant the geographical region as well. It does not limit the geographical region?

A. No, so that is completely universal. So I can take that to New Zealand.

THE EXAMINER: I was going to say: Edinburgh and Glasgow are in Scotland, if you don't know, so that is why I referred to it as "Scots qualified".

BY MR. ASSAAD:

Q. Now, after you -- following 2002, you said that is when you became a consultant?

A. Yes.

Q. And --

Page 172

MICHAEL R. REED

A. Maybe 2003, I think I became a consultant.

Q. And before that, what would your title have been before a consultant?

A. A specialist registrar, I think we were called.

Q. And what is the difference between a special registrar and a consultant?

A. So as a specialist registrar, you are still working under the governance of a consultant; whereas once you are a consultant, you are an independent practitioner, albeit within the constraints of the health service and its given governance structures. But I am an autonomous practitioner.

Q. Okay. So if we had to relate it to -- are you familiar with the United States system, with a -- with the trainee, the residency, and then there's also an attending at a university hospital?

A. Yes, so it would be an attending position. If I have now -- I think that's what you would call it. And the resident would be the specialist registrar. The difference is that your residency is very short, whereas ours is very, very long in comparison.

Q. Understandable.

And as a consultant, do you train specialist registrars?

Page 173

MICHAEL R. REED

A. Yes.

Q. And do you currently train?

A. Yes; and I am currently training program director, so I am head of training in the North East. So that's 67 trainees that are, if you like, under my auspices.

Q. And those 67 trainees are trainees for trauma and orthopaedics?

A. Yes.

Q. You said "program director". Are those individuals that are in the hierarchy below you, but assist you in training those 67?

A. Yes, so there are people -- I wouldn't say they are below me, but there are people, attending surgeons of equal rank who will generally train one individual each, if you like; that sort of make-up.

So we have got a wide body of attending surgeons who train specialist registrars in my region and I am head of training. I would not say I am in charge of them. I think they have made that pretty clear, that I wasn't.

Q. And those program directors are also consultants; correct?

A. Yes. So I am a program director and I am a consultant, yes.

Q. Okay.

Page 174

MICHAEL R. REED

Are you a member of any national organizations, in respect to trauma and orthopaedic surgery?

A. Yes. So I am a fellow of the British Orthopaedic Association and the -- I am a member of the British Hip Society as well.

Q. Are you a member of any international organizations?

A. Not from memory.

Q. Just out of curiosity. I remember you mentioned during Mr. Gordon's questioning to you that you gave a presentation to the American Academy of Orthopaedic Surgeons in San Diego; is that correct?

A. Yes, it sounds like it's correct. I can't remember -- I actually can't remember what it was. But I did say I gave one. I did go to that meeting for sure. I don't remember what presentation it is. I give a very -- I do a huge amount of presentations.

Q. And have you given many presentations -- or have you given any other presentations in the United States?

A. So in 2012, I represented Britain in a traveling fellowship of orthopaedic surgeons; so there was four surgeons from Britain selected to tour round the United States, giving talks.

Q. Do you know Dr. Parvizi?

A. Yes.

Page 175

MICHAEL R. REED

Q. Do you know him personally?

A. Yes.

Q. Were you part of the consensus that was formed among the orthopaedic surgeons internationally?

A. I was not part of the last one, but I am part of the one that is coming up.

Q. And you know the consensus I am speaking about?

A. Yes, the peri-prosthetic joint infection consensus, yes.

THE EXAMINER: Sorry, can you repeat that?

A. Okay. So there's probably now -- I think in 2013, there was a meeting held in the United States to agree on risk factors for peri-prosthetic infection; so infection of a joint replacement. And in fact, I didn't go to the consensus meeting but I did contribute to it, actually on theater and laminar flow. Maybe even on forced air warming. But certainly on laminar flow.

So I wrote some of the text for it, which I think they subsequently voted on in the big meeting. And that meeting is coming round again, and I will be going -- I think it is next year or the year after.

BY MR. ASSAAD:

Q. We are talking about work group 4, correct, dealing with particles and laminar flow and forced air warming?

A. Sounds correct.

Page 176

MICHAEL R. REED

Q. I think you cited two before in some of your articles?

A. Right, yes. I did provide some text for it. I don't genuinely know how far that got.

THE EXAMINER: It is a consensus document, is it?

A. Yes. So it is -- it is a sort of highly publicized consensus document of, if you like, world experts, mainly U.S. focused, but still there's a few U.K. people that go.

BY MR. ASSAAD:

Q. And have you seen the consensus, the final version of it, the one that was prepared in 2013?

A. Yes, I have seen it.

Q. And do you understand that 3M was a sponsor of the consensus?

A. I hadn't realized that, but ...

Q. And it's -- based on your CV, you have received awards in the event; correct?

A. I have received awards.

Q. Yes.

A. Yes, I suppose I have. I am trying to think what.

THE EXAMINER: Where are they listed?

MR. ASSAAD: It might not be on his CV. I know we talked about it, but I thought I saw it on his CV.

BY MR. ASSAAD:

Page 177

MICHAEL R. REED

Q. Well, I don't see it on your CV, but have you received any awards in orthopaedic surgery?

A. I received the Program Director of the Year Award last year. So that's the national award for theoretically the best program director in that job we just talked about, of training the trainees.

I can't remember any others. You will have to prompt me.

Q. All right. And I can tell you, you have had publications, such as peer reviewed articles. You have done presentations, book chapters and you have been a reviewer for publications and given lectures; correct?

A. Yes.

Q. All on orthopaedic surgery; correct?

A. Yes.

Q. And did any of them have to do with peri-prosthetic joint infections?

A. Quite a large number of book chapters and papers would relate to that.

Q. Just so we are on the same definition. Is there a difference between a wound infection in your mind and a peri-prosthetic joint infection?

A. I mean, I think a wound infection is a more general term that can refer to someone that's had surgery generally

Page 178

MICHAEL R. REED

and has got an infection; whereas a peri-prosthetic joint infection, we will call it "PJI" maybe, PJI, is specific to when you have an implant in place, a hip replacement, for instance.

Q. Like, for example, the McGovern study which we discussed a lot today, or you discussed a lot today. That dealt with PJIs; correct?

A. Correct.

Q. Not superficial wound infections; correct?

A. Correct, yes.

Q. And that is a big difference to treat a superficial wound infection, as compared to a PJI; correct?

A. Yes. I mean, it is a world apart.

Q. And we talked about peer review. And just in your own words, would you agree -- or strike that.

Would you agree that the peer review process is a rigorous process?

A. Yes.

Q. And based on my review of your -- of the literature that was on Google Scholar, it is my understanding that you have done research on methods to reduce peri-prosthetic joint infections?

A. Yes.

Q. And you have done research on operating theater methods

Page 179

MICHAEL R. REED

to reduce peri-prosthetic joint infections?

A. Yes.

Q. And you have actually done research on draping methods to reduce peri-prosthetic joint infections?

A. On what methods?

Q. Draping methods?

A. Draping methods. Certainly gowning methods, yes.

THE EXAMINER: That is slightly different?

A. Well, draping I think is what you put on a patient; whereas gowning is what you put on yourself.

THE EXAMINER: Quite.

A. But yes.

BY MR. ASSAAD:

Q. You have also done research on prophylactic antibiotics to reduce PJIs; correct?

A. Correct.

Q. You have done research on thrombo-prophylactics to reduce PJIs; correct?

A. I am not sure about to reduce it, but its impact on, yes.

Q. And going back, because I am not sure if we have discussed this, or if you discussed it in the direct.

Just for the ladies and gentlemen of the jury back home, what is peer review and why is it important?

Page 180

MICHAEL R. REED

A. So peer review is when you send an article that you have written. You send it to the journal and they will send it, normally anonymously, to several people who will -- who are also experts in that area, who will read it and decide. Normally they will decide that it's not good enough for publication. If they -- if they like it, then they will generally send it back for changes, suggestions. And very, very rarely, they will take it first, first hit. So it is important obviously; it is a quality indicator. It is a quality measure.

Q. Quality control for an article?

A. Yes.

Q. Reaching the -- your other colleagues in the field; correct?

A. Yes.

Q. Do you follow any certain -- or do you subscribe to any certain peer review journals?

A. So I subscribe to the Bone and Joint Journal, and have access to a large number of journals through my university network and the hospital network.

Q. And you said you were a reviewer for some of those journals?

A. I am a reviewer for, in the last year, the Bone and Joint Journal. Yes, I think I review for probably three

Page 181

MICHAEL R. REED

or four journals. Certainly in the last three or four years, I've reviewed for three or four journals.

Q. Would it be fair or accurate to state that you devoted most of your research to PJIs?

A. Certainly to joint replacement. I would say a large amount is PJI. I do also do other things on outcomes, but yes, largely -- quite a large body of work would be prosthetic joint infections.

Q. And the purpose of that is you are trying to make joint replacements safer for the patient?

A. Yes.

Q. Because safety is paramount to any methods you ascribe to, with respect to the patient; correct?

A. Yes.

Q. And you would expect that safety should be paramount to a medical device manufacturer that markets and sells devices to your hospital; correct?

A. Yes.

Q. And PJI is a serious complication and can be catastrophic; correct?

A. Yes.

Q. You can have multiple surgeries?

A. Yes.

Q. You mentioned before, amputations?

Page 182

MICHAEL R. REED

A. Rarely, but to get to that point, there is a huge number of surgeries normally as well.

Q. And potentially it could cause death?

A. Yes. Well, it does cause death. I mean, there is a definite association with mortality. It reduces your life span.

Q. Do you consider yourself an expert in peri-prosthetic joint infections?

A. Well, in, you know, the view that I have been invited to the international consensus perhaps, and I do speak frequently on it at meetings. I spoke yesterday in Manchester on it. So yes, I speak quite frequently on it.

THE EXAMINER: And my understanding is that it is not that there is a significant percentage or proportion of infections in this surgery. It is because of the severity of the cost to --

A. Exactly. So it is the severity of the complication which is just game changing for most patients. It is a terrible, terrible complication.

BY MR. ASSAAD:

Q. And do you consider yourself an expert with respect to the causation of peri-prosthetic joint infections?

A. I think "expert" is maybe for someone else to judge, but

Page 183

MICHAEL R. REED

I do know a lot about it and I have spent a lot of time researching it.

MR. ASSAAD: We need to go off the record, because of the change of CD.

THE VIDEOGRAPHER: This is the end of tape number 2 in the deposition of Michael Reed. Going off the record at 4:44.

(4:44 pm)

(Break taken.)

(4:49 pm)

THE VIDEOGRAPHER: This is the beginning of tape number 3 in the deposition of Michael Reed. Going on the record at 4:48.

BY MR. ASSAAD:

Q. Mr. Reed, we can agree that you need a bacteria to cause a peri-prosthetic joint infection; correct?

A. Yes.

Q. And we can agree that because of the implant, you need very few bacteria to cause a peri-prosthetic joint infection; correct?

A. Correct.

Q. Contrary to a wound infection, where you might need millions; correct?

A. So if you don't have an implant in situ, then you can

Page 184

MICHAEL R. REED

have many, many more bacteria on the wound without getting an infection. So yes, it is much more important when you have got an implant.

Q. So an implant is highly susceptible to a bacteria and the cause of a peri-prosthetic joint infection mainly because of biofilm; correct?

A. Yes, so biofilm is a slime that the bacteria produce that protect it from antibiotics and other mechanisms the body might have to rid the infection. So yes, it is very -- it is driven by biofilm, we think, the difficulties in getting rid of the infection.

Q. And you would agree with me that as a result -- strike that.

You would agree with me that most, if not all of the peri-prosthetic joint infections occur when bacteria gets to the implant during the perioperative period; correct?

A. I am not sure we know that. That's -- but that is sort of an accepted philosophy. But I don't think we know that for sure, in actual fact. But that is the dogma.

THE EXAMINER: You referred to the peri ...?

BY MR. ASSAAD:

Q. Peri, during the surgery.

THE EXAMINER: I see, during the operation.

Page 185

MICHAEL R. REED

BY MR. ASSAAD:

Q. When you say that is the accepted philosophy, that is the main consensus among most orthopaedic surgeons; correct?

A. Yes.

Q. And because of the biofilm, it is very difficult to treat these peri-prosthetic joint infections through medication; correct, such as antibiotics?

A. Yes. Essentially you can't get rid of an infection with antibiotics alone.

Q. Because there is no vascularity to the joint?

A. Yes, because -- because bacteria and biofilm become very protected by the slime, and so you need about a thousand times the dose of the antibiotic for it to work, and you can't deliver that much antibiotic to the patient.

Q. Have you heard of the term "chain of infection"?

A. Can you -- can you rephrase that?

Q. Yes, I can actually. Basically, for an infection to occur, you have to have an infectious agent, a reservoir, a portal of exit, a mode of transportation, a portal of entry and a susceptible host. Have you heard that described before?

A. Yes.

Q. And for example, so with respect to the infectious

Page 186

1 MICHAEL R. REED
 2 agent, that would be bacteria; correct?
 3 A. Yes.
 4 Q. And the reservoir in the operating room, that could be
 5 the patient; correct?
 6 A. Yes.
 7 Q. It could be the surgeon?
 8 A. Yes.
 9 Q. It could be the assistant?
 10 A. Yes.
 11 Q. It could be the scrub nurse?
 12 A. Yes.
 13 Q. It could be the Bair Hugger?
 14 A. Yes.
 15 THE EXAMINER: It is just the source of the infection.
 16 MR. ASSAAD: Yes.
 17 THE EXAMINER: It could be hundreds of things probably.
 18 MR. ASSAAD: The most likely things I am talking about,
 19 actually.
 20 THE EXAMINER: Right.
 21 BY MR. ASSAAD:
 22 Q. And you would agree with me that the mode of transit --
 23 the transmission of the bacteria in the operating room
 24 would be particles; correct?
 25 A. Yes, I think that would be fair.

Page 188

1 MICHAEL R. REED
 2 can.
 3 Q. And that's because of the biofilm; correct?
 4 A. Well, I think it's because some bacteria are slow
 5 growing, that you can get infections that last that
 6 long. But what sustains them is the biofilm. That's
 7 what -- that's what allows them to continue to grow and
 8 become problematic, is that with being in biofilm, they
 9 are not able to be treated by antibiotics or by the host
 10 defenses. That is why they can take so long.
 11 Q. In your practice, have you ever had a patient come in
 12 that had a peri-prosthetic joint infection that had the
 13 primary surgery done more than six months?
 14 A. Yes.
 15 Q. More than a year?
 16 A. Yes.
 17 Q. More than two years?
 18 A. Yes.
 19 Q. How long?
 20 A. Well, people can present at any point with an infected
 21 joint replacement.
 22 THE EXAMINER: I think he was asking: what was the longest
 23 period between primary and return?
 24 BY MR. ASSAAD:
 25 Q. If you know. If you don't know, it's ...

Page 187

1 MICHAEL R. REED
 2 Q. Such as skin squames; correct?
 3 A. (Nods.)
 4 Q. You have to say "yes".
 5 A. Yes.
 6 Q. Or another name for it might be "fomites"; correct?
 7 A. Yes, I don't think we have a definite understanding of
 8 actually where the infection comes from. But these are
 9 the commonly accepted things.
 10 THE EXAMINER: What about if you had a dirty instrument?
 11 Would that involve particles or not?
 12 A. Well, I mean, there would be -- in particle form,
 13 I guess on the instrument; but yes, you could certainly
 14 spread infection by instruments that haven't been
 15 sterilized and that does happen from time to time.
 16 BY MR. ASSAAD:
 17 Q. But that wouldn't meet the standard of care; correct?
 18 A. Correct.
 19 Q. The standard of care would have sterile conditions;
 20 correct?
 21 A. Yes.
 22 Q. Now, with respect to a peri-prosthetic joint infection
 23 to reveal itself, that might take a couple of years;
 24 correct?
 25 A. It can take that long. It is relatively rare, but it

Page 189

1 MICHAEL R. REED
 2 A. Well, I have certainly seen plenty of people that had
 3 a joint replacement 15 years ago that come in with
 4 an infection. But then the question is whether it was
 5 caused during the primary operation or not, or whether
 6 it is a new infection which has gone through the
 7 bloodstream. But yes, it can present at any time, but
 8 it commonly presents early, in the first few months.
 9 Q. Okay.
 10 THE EXAMINER: Is there an alternative to removal of the
 11 implant and replacement?
 12 A. So there's various criteria that you might use to make
 13 decisions. But one operation you can do is to open up
 14 the wound and literally scrub it and clean it and cut
 15 away all the affected tissue. The idea is to try to get
 16 rid of the biofilm, and then give them antibiotics which
 17 hopefully are targeted on the bacteria.
 18 And in a proportion of cases, perhaps 60 percent of
 19 cases, you might be able to make that the only extra
 20 operation. But many patients will go on to having
 21 further very significant surgery to remove the implant.
 22 THE EXAMINER: So if you try that route and it doesn't work,
 23 the patient is faced with at least four operations;
 24 a third to remove the implant and a fourth to replace,
 25 and a fifth implant?

Page 190

MICHAEL R. REED

A. Yes, at least, yes.

THE EXAMINER: I hope my hips remain in one piece.

BY MR. ASSAAD:

Q. In your practice, you have had patients that may have had more than five or six surgeries to remove an infection; correct?

A. Yes.

Q. Though it is uncommon, it is not rare to have that many surgeries?

A. It is not rare. I think my record is about 14 or 15 operations.

Q. Now, we're going to get into discussing your publications that we have discussed before, and I am going to ask you many questions. And if you give an opinion, I am not asking for an expert -- but just if you give an opinion, I want to make sure that it is within a reasonable degree of medical probability, similar to a medical diagnosis. I don't want you to guess or anything. Is that fair?

A. So, just so I am clear. Are you saying that if it is more than 50 percent, you want me to say "yes", or more than 20 percent?

Q. For example, you were asked questions like: does, for example, MSSA screening reduce infections? And you

Page 191

MICHAEL R. REED

said: well, there is no evidence. When you give that opinion, I want that to be with a reasonable degree of medical probability.

The reason I am asking that is because under our Federal Rules of Evidence, without having that limit as a standard, it would be inadmissible in court. So it is greater than 50 percent; fair enough?

A. Okay.

Q. And if you can't make that opinion, if you are unsure, please let me know and we don't have to -- you don't have to answer the question. Fair enough?

A. Yes. And just so I am clear: are you talking about now or in 2010 or '11?

THE EXAMINER: You are not here to give opinion evidence today. You are here to give evidence about the facts and matters surrounding the production of these papers.

A. So my answers relate to what we knew in 2010 or '11?

BY MR. ASSAAD:

Q. Or whatever period the article was.

A. Okay.

Q. Fair enough?

A. Yes.

Q. Now, part of the McGovern study dealt with disruption of the unidirectional airflow; correct?

Page 192

MICHAEL R. REED

A. Yes.

Q. Are you familiar with the Legg studies?

A. Somewhat familiar.

Q. Do you know Andrew Legg?

A. I have met him.

Q. Do you know Mr. Hamer?

A. Yes, I do.

Q. Have you had any discussions with them about their studies?

A. We have definitely discussed it in the past. We haven't discussed it in any detail recently, in the last probably three or four years. I don't think we have discussed it.

Q. But you are aware that their studies showed an increase in particle count on the surgical site; correct?

A. Yes.

Q. And I think in some of your articles, you cite those studies; correct?

A. (Nods.)

Q. Is that correct?

A. Yes.

Q. And would you agree with me that the longer the surgery exposure, there's more -- there is likely more exposure to particles?

Page 193

MICHAEL R. REED

A. So the longer the operation, the higher the infection rate. That is accepted. We don't know quite why that is and whether that is linked to obesity.

But yes, in broad terms, if your wound is open and that's when the particles get into it, then clearly there will be a temporal link between the wound being open for a length of time and an infection.

THE EXAMINER: What sort of -- if there can be an average hip replacement operation, what sort of time are we talking about?

A. For a slim patient, probably an hour, an hour and a quarter, something like that.

THE EXAMINER: And with an obese patient, it increases?

A. Yes.

BY MR. ASSAAD:

Q. And speaking about patients themselves, the patient is a susceptible host, right, to the infection; correct?

A. Yes, yes.

Q. And some hosts, some patients have more difficulty fighting off infections than others; correct?

A. Yes.

Q. Obese patients or underweight patients have more difficulty fighting off bacteria; correct?

A. Yes.

Page 194

MICHAEL R. REED

Q. Perhaps smokers?

A. Yes. I mean, I would say definitely smokers, if you base it on the RCTs.

Q. Diabetics. In one of your papers, you cited to a study that showed there was no difference in PJIs in people with type 1 or type 2 diabetes; is that correct?

A. Yes, so in our own series we have not actually found a link with diabetes and infection. But most series would show a link.

Q. And with all these co-morbidities that we are discussing, at the end of the day, you still need the bacteria to enter into the host to cause the infection; correct?

A. Yes.

Q. Okay. Smoking does not cause bacteria to get into the implant; correct?

A. Correct.

Q. So does --

MR. HOLL-ALLEN: Forgive me for interrupting. It does seem to me that we are getting into the area of opinion evidence which is not clearly related to the individual studies. I question whether these issues are within the scope of the defined studies or whether the answers to these questions are required in order to understand the

Page 195

MICHAEL R. REED

studies.

MR. ASSAAD: If you look at my tab 7, which is one of the studies that I have -- which he has authored. It talks about obesity, diabetes, smoking.

THE EXAMINER: Yes, but just because he has authored an article on that topic, it does not necessarily bring it into the scope.

MR. ASSAAD: Okay.

THE EXAMINER: Hang on, hang on. That is not necessarily an end of the matter.

MR. HOLL-ALLEN: Sir, the order, as with the orders in the other cases, identifies certain specified other studies. This is paragraph 25.

THE EXAMINER: Yes, it does refer at 4 and 5 to factors that influence infections in general orthopaedic surgery and 5, infections and general practices. I think that we are in the area of factors that influence infection. Does smoking influence infection? It does seem to me a proper question. I -- you have put a marker down.

MR. HOLL-ALLEN: And may I very briefly, because I don't want to hold up matters, say that I specifically objected to paragraph 4 in front of the hearing before the Senior Master; and the Master let it in, in part on the understanding that it might well include matters of

Page 196

MICHAEL R. REED

opinion evidence, but that was a matter that could be taken up at the time of the deposition.

So I have registered my concerns.

THE EXAMINER: You have. I am sure Mr. Assaad has heard and I am sure he will --

MR. ASSAAD: I am --

THE EXAMINER: -- restrict himself to paragraph 4 of the schedule B.

MR. ASSAAD: I will, and ...

BY MR. ASSAAD:

Q. You are familiar with the Belani study; correct?

A. Yes.

Q. And you are an author in the Belani study; correct?

A. Yes.

Q. With respect to the McGovern study, that just dealt with the primary, total knee and total hip arthroplasty; right?

A. McGovern was hip and spine. Belani was knee. That's my recollection.

THE EXAMINER: Where is the Belani?

MR. ASSAAD: Tab number 1.

THE EXAMINER: I don't have ...

MR. ASSAAD: I am sorry, McGovern.

THE EXAMINER: McGovern?

Page 197

MICHAEL R. REED

MR. ASSAAD: Yes.

BY MR. ASSAAD:

Q. We could keep that in there, but just for the record, I would like to mark tab 1, exhibit number 8. If you would like to put a sticker on the McGovern study in tab number 1?

THE EXAMINER: It is already exhibited.

A. This is the McGovern study, not the Belani study.

MR. ASSAAD: That is in a different case or a different deposition. I am going to mark it in this deposition for the court, so I can ...

A. This is McGovern?

MR. ASSAAD: Yes.

(Exhibit Reed 8 marked for identification.)

THE EXAMINER: She is marking the one in your file.

MR. ASSAAD: Yes.

BY MR. ASSAAD:

Q. If you look at Reed 5 at the bottom, there is a graph at the top of the page, table 1.

The data that was provided is here(?); is that correct?

A. Yes. Sorry, I thought you were referring to the lab-based study in this paper, as opposed to the clinical study.

Page 198

MICHAEL R. REED

Q. I am sorry?

A. I thought when you were referring to the lab-based study -- because in the McGovern paper the lab-based study, if you like, the one not involving patients, was on -- was on hips.

Q. Sure, the airflow or the bubble tests.

A. Yes, those tests. But the clinical paper, you are quite correct, is on both.

Q. And if you don't understand my question or you are getting confused, let me know. We will try to be on the same page, because I want to have a clear record here.

A. Yes.

Q. And those surgeries that had been dealt with: primary, total knee and total hip arthroplasty?

A. Yes.

Q. Which is less time for surgery than revision; correct?

A. Correct.

Q. Revision surgeries have higher infection rates; correct?

A. Correct.

Q. In some of your articles, you have also referred to the Sessler study. Are you familiar with the Sessler study?

A. Yes. So --

THE EXAMINER: How is that spelt?

MR. ASSAAD: S-E-S-S-L-E-R.

Page 199

MICHAEL R. REED

A. You will need to tell me which Sessler study, because he has been --

MR. ASSAAD: The Sessler Olmsted 2011 study.

A. What is the title of the paper?

Q. 2011?

THE EXAMINER: No, the title.

BY MR. ASSAAD:

Q. Oh, the title.

A. He has been fairly prolific over the years.

Q. Do you know Dr. Sessler personally?

A. I don't.

Q. Do you --

A. I know -- I know he has done some studies for Arizant. I don't know him.

Q. It is titled:

"Forced-air warming does not worsen air quality in laminar flow operating rooms."

Do you know that study?

A. I am not very familiar with it, I am afraid. Have you got it here?

Q. I don't think I -- since your name was not on it, I didn't ... you have cited two, but I can give you a blank copy.

A. Sure.

Page 200

MICHAEL R. REED

Q. If you -- going back to ...

I want to turn to tab number 13.

THE EXAMINER: I ...

MR. ASSAAD: You are not going to have this one.

THE EXAMINER: Not even what you sent me electronically?

MR. ASSAAD: Oh, electronically, yes. It would be page number -- I would like to mark this as exhibit 9.

(Exhibit Reed 9 marked for identification.)

BY MR. ASSAAD:

Q. If you go to the second page.

THE EXAMINER: So the index is a blank document. The other says that the -- oh, the document. Yes, sorry. Where are we going?

MR. ASSAAD: The second page. Do you know what page it is on? I gave you an index. It is Reed 116.

BY MR. ASSAAD:

Q. Have you seen this e-mail before?

A. I saw it in this -- this week or two.

Q. This is an e-mail dated March 8, 2012.

A. Yes.

Q. Oh I am sorry, December 2nd, 2011, from you to --

A. Yes, I do remember sending it, yes.

Q. Can you please describe this e-mail?

A. Right. I wish it was a bigger font. So my recollection

Page 201

MICHAEL R. REED

is that this was an inquiry that I had from a center in the U.S. I think actually in Minneapolis. And they are asking about a study we have done and I am providing them with some updates. I think I have taken the trouble to put my disclosures in and where it's been presented. And I have offered to put them in touch with Mark Albrecht, who could come and demonstrate the issue, which I think would probably be fairly easy to demonstrate in a theater.

Q. And were you in Minneapolis at any point in time during this period?

A. So I was in Minneapolis in 2012, so maybe in, I think, May 2012.

THE EXAMINER: Look at the last sentence of your e-mail.

A. There you go. June 2012. That was when I mentioned I was doing a lecture tour of the States and I knew it was going through their town in June, by the look of it.

BY MR. ASSAAD:

Q. Okay. And you are aware that this e-mail was forwarded on to 3M?

A. I wasn't aware of that until yesterday.

Q. Okay. At any point in time, when 3M was made aware, I guess they were made aware in March 13, 2012, did you ever get a phone call or any type of e-mail from 3M

Page 202

1 MICHAEL R. REED
 2 saying: "Hey, we want to know more about the data that
 3 you have obtained in the McGovern study?"
 4 A. No.
 5 Q. And you talk about more data on 400 more patients,
 6 around 400 more patients; correct?
 7 A. Yes.
 8 Q. And you -- and if you look at your e-mail, you write:
 9 "You will see the effect is present for knees (0.6
 10 vv 1.6%) as well as hips (1.3 vv 5.5%). The effect has
 11 been sustained."
 12 What did you mean by "The effect has been
 13 sustained".
 14 THE EXAMINER: Sorry, where is that?
 15 A. So it just meant that we continued to see low rates of
 16 infection.
 17 BY MR. ASSAAD:
 18 Q. For the Hot Dog?
 19 A. Yes. Well, yes.
 20 Q. Okay. Or the conductive warming device which was the
 21 Hot Dog; right?
 22 A. Yes.
 23 Q. So even after you published the McGovern study, you
 24 continued to obtain data to see whether the effect could
 25 be sustained; correct?

Page 204

1 MICHAEL R. REED
 2 don't have here is peer review. But on the face of it,
 3 it looks, you know, like an impressive reduction.
 4 Q. There was discussion with respect to -- during the
 5 direct examination, about the change in antibiotics
 6 during the study period, with respect to forced air
 7 warming and the conductive fabric device. Do you recall
 8 that testimony, that discussion?
 9 A. Yes.
 10 Q. Were you aware that Mr. Albrecht ran the numbers to
 11 determine the differences in the reduction rate between
 12 the different antibiotic protocols?
 13 A. Only when I read this, you know, in the last couple of
 14 weeks.
 15 Q. Were you aware that there was no statistical difference
 16 between antibiotic protocol 1 and protocol 2?
 17 A. Not prior to the last couple of weeks.
 18 Q. If that's true, would you agree with me that the change
 19 in antibiotic protocol had no statistical significance
 20 in the infection rates in the McGovern study?
 21 A. So on the face -- on the basis that you have only got
 22 those two things involved, the antibiotics -- one
 23 antibiotic versus another, then this appears to show
 24 that.
 25 Q. And if that statement is true, you would agree with me

Page 203

1 MICHAEL R. REED
 2 A. Yes.
 3 Q. And at any time, did you run the statistical analysis
 4 regarding that data?
 5 A. Yes. Well, yes, I did.
 6 Q. Okay. Did you get the same -- a P value that still
 7 showed that the results were significant?
 8 A. So my recollection is that the P value at that point was
 9 very significant. I think it is somewhere in this
 10 documentation.
 11 Q. If you look at it, in the following tab, 14. Reed 118.
 12 A. Yes. So I haven't seen this before, although it was
 13 interesting as an analysis. But ...
 14 Q. Okay. Can we mark this as exhibit number 10?
 15 THE EXAMINER: "This" being?
 16 MR. ASSAAD: Reed 118.
 17 THE EXAMINER: Just that page?
 18 MR. ASSAAD: Yes.
 19 (Exhibit Reed 10 marked for identification.)
 20 BY MR. ASSAAD:
 21 Q. Why do you say this was very interesting?
 22 A. Well, it is the first time I have seen this, in
 23 different centers, being collated, if you like. So it
 24 was interesting that on the face of it, at least, they
 25 have had a similar experience. But of course, what you

Page 205

1 MICHAEL R. REED
 2 that the change in antibiotic protocol would not be
 3 considered a confounding factor in the McGovern study?
 4 MR. GORDON: Object to the form of the question.
 5 THE EXAMINER: This is getting perilously close to asking
 6 him to give his opinion.
 7 MR. ASSAAD: In the McGovern study, he spent much time
 8 showing --
 9 THE EXAMINER: I know he did, but you are now introducing
 10 an additional factor which is something which has only
 11 come to his attention recently.
 12 MR. ASSAAD: Fair enough.
 13 THE EXAMINER: And asking him how, in his opinion, it
 14 affects matters, which I think is teetering on the edge.
 15 A. So on the basis of the information we have got in front
 16 of us, it looks as if there wasn't a difference between
 17 the two antibiotic regimes. I haven't had the ability
 18 to sort of look at this in detail. It is not my work;
 19 but clearly it's done about my work.
 20 MR. ASSAAD: I am not going to go any further with you,
 21 then, with respect to that question, then.
 22 BY MR. ASSAAD:
 23 Q. But you agree with me that the change in antibiotics
 24 does not add any sort of contamination to the sterile
 25 field; correct?

Page 206

MICHAEL R. REED

MR. GORDON: Object to the form of the question.

A. Yes. You wouldn't expect the antibiotic choice to contaminate the operative field.

BY MR. ASSAAD:

Q. There is nothing about changing the antibiotics that would increase the bacteria in the sterile field during the operation?

A. No.

Q. Now, based on your McGovern study, you agree that at the time, your opinion, based on the McGovern study, was that convection currents from the forced air warming device, the Bair Hugger here in this situation, had an effect on the unidirectional airflow in the operating room; correct?

A. Yes.

Q. And in fact, the correlation -- or the convection currents added particles or showed that there was air coming from underneath the operating room table into the surgical site; correct?

A. Yes.

Q. Did you see any bubbles going in the operating room, where the back table would be or the implant is, and the instruments?

A. I can't honestly recollect whether rogue bubbles would

Page 207

MICHAEL R. REED

have gone -- our back table would always be within the laminar flow. I don't know how things are done in the U.S. But -- I don't know. Probably --

Q. Is your back table close to the surgeon or -- or close to the scrub nurse or ...?

A. Yes. So everything is within this 2.4 meter squared canopy. We are pretty strict on that.

Q. So at the time, you didn't formulate an opinion on whether or not the disruption in the airflow caused by the Bair Hugger could contaminate the sterile instruments or the sterile implant?

A. So I can't confirm or refute that. It might be something to ask Paul McGovern who was in the room more frequently.

Q. What is a colony forming unit?

THE EXAMINER: A ...?

BY MR. ASSAAD:

Q. A colony forming unit, a CFU.

A. So this is -- yes, this essentially is a bacteria which goes on to cause an infection.

Q. So viable bacteria; correct?

A. Yes.

Q. Is there a correlation between particles and CFUs?

A. We certainly can't have any colony forming units without

Page 208

MICHAEL R. REED

any particles. We think that lots of particles are bacteria. In fact, there is, I think, published work on them, on how many particles will carry bacteria. I think it's in the region of 10 percent, but it's -- that's my recollection of the literature.

Q. Do you agree with me that airborne contaminants are the largest single contributor to infection; correct?

A. Yes, I think that's true. That's certainly what most orthopaedic surgeons would believe.

Q. And you would agree with me that a person would shed 1 billion skin cells daily?

A. That's what the literature says.

Q. That's what it would be --

A. Yes.

Q. And you just testified that 10 percent of those other particles would be carrying colony forming units; correct?

A. Correct. That is what the literature tells us.

Q. So as the colony forming units -- or the particles increase, it would be safe to assume that the amount of bacteria would increase?

A. Yes.

Q. So would you agree that the Bair Hugger, based on your research in the McGovern study and the Belani study,

Page 209

MICHAEL R. REED

increases particle counts?

THE EXAMINER: I don't think I want him to agree. I want him to answer whether that was a result of your research.

A. So there are several studies that show -- that compare forced air warming with conductive fabric warming. Many of these are on the table today. And yes, you will get more -- more contamination, if you like, from the sides if you are using forced air warming. I think there's numerous studies that show that.

BY MR. ASSAAD:

Q. And more contamination of particles would mean an increase of the bacteria in the surgical site; correct?

A. That's --

MR. GORDON: Object to form.

A. One would assume so.

BY MR. ASSAAD:

Q. Well, if 10 percent of the particles -- you just testified, if you increase the particles by five or six times, you would have five or six times more bacteria?

A. Correct. That's ...

MR. GORDON: Object to the form of the question.

BY MR. ASSAAD:

Page 210

MICHAEL R. REED

Q. And would you agree with me that an increase of the bacteria in the surgical site would cause a greater chance of PJI by the susceptible host?

MR. GORDON: Object to the form of the question.

THE EXAMINER: What I really want to know is: was this as a result of the research they carried out, rather than -- when you ask him to agree with you, you are asking him in effect to express an personal opinion.

It is just rewording the question to say: did your studies show that ...

MR. ASSAAD: I would like to have back-ups, as a cross-examiner, of the document I am looking at.

BY MR. ASSAAD:

Q. Did any of your studies indicate that the increase in bacteria around the surgical site increases the likelihood of a peri-prosthetic joint infection by the susceptible host?

A. So what we have shown is an association with, you know, what we did for a period of time and then we changed, and then we had a change in our infection rates; with the caveats that we had changes to our practice. Apart from that, as we have detailed and as we have put in the paper.

Q. Besides -- and you have spent much time on the color

Page 211

MICHAEL R. REED

graph and we will go over it a little bit, maybe go over it.

But is there anything in that graph or the changes in your practices that you could point to, that would cause increased particles into the surgical site, besides the forced air warming device?

THE EXAMINER: Is this the one you mean?

MR. ASSAAD: Yes.

A. No, there wouldn't be anything else that you would be suspicious of.

BY MR. ASSAAD:

Q. And going back to the other issue of the McGovern article that counsel has raised today.

Was the -- it was the xarelto issue with respect to changing the thrombo-prophylactics; correct? Do you recall doing a study which actually looked at the return to theater, in which you compared a low molecular weight heparin to xarelto and determined the infection rates?

A. Yes. So that was led by a colleague of mine, but I was part of the group. And the primary outcome measure was return to theater, not infection. But it didn't actually show a significant difference in infection rates, but ...

Q. Can you turn to tab 8?

Page 212

MICHAEL R. REED

A. Tab 8, yes.

THE EXAMINER: Page?

MR. ASSAAD: Page Reed 84. Let's mark that as exhibit number 11.

THE EXAMINER: The page?

MR. ASSAAD: No, the entire article. Reed 84 to Reed 99. (Exhibit Reed 11 marked for identification.)

BY MR. ASSAAD:

Q. Can you please describe this article? What are we looking at in exhibit 11?

A. Right. Well, I will certainly describe what we did and then if you give me a minute, I will describe what we found, because there is a lot of detail in here with the various types of complication.

Q. Just for the record, while we are looking at it, I am going to read the title, just so we have it clear for the ladies and gentlemen of the jury.

A. So this title -- this paper is entitled:

"Wound complications following rivaroxaban administration -- a multi-centre comparison with low molecular weight heparin for thromboprophylaxis in lower limb arthroplasty."

So in basic terms, this is people that are having a hip or a knee replacement and does -- does giving

Page 213

MICHAEL R. REED

rivaroxaban or a low molecular weight result in more complications?

Q. Now, I need to confess to you. When I pulled up this document, it was in production by Nachtsheim; but actually yesterday, I actually found the published version which was published in the Journal of Bone & Joint Surgery in 2012; is that correct?

A. Yes, I think it was published in the American journal, the American Bone & Joint --

Q. I would offer you to look at the published version, if you would like, unless there is any objection by your counsel.

MR. HOLL-ALLEN: No.

THE EXAMINER: This is not the published version?

MR. ASSAAD: No, I found the published version.

A. Is it the same? I don't know.

BY MR. ASSAAD:

Q. I believe it is. It has the same numbers.

A. Thank you. Okay.

Q. Let's mark this as exhibit 12, please.

(Exhibit Reed 12 marked for identification.)

THE EXAMINER: Are the two first named authors from your trust?

A. They were at that time.

Page 214

MICHAEL R. REED

THE EXAMINER: They were at that time?

A. Yes. So this -- briefly, this is a paper where we asked other hospitals around the country that had changed similarly to us, to get in touch; and then we analyzed their data remotely to see what the complications had been.

BY MR. ASSAAD:

Q. And xarelto does not increase increased particles or bacteria to the surgical site; correct?

A. Correct.

Q. I would like you to refer to page 1556.

(Off the record remarks.)

Q. Now, Mr. Reed, you would agree with me that if someone has a peri-prosthetic joint infection, they would have to be returned to the operating room; correct?

A. Almost certainly. Very rarely not.

Q. Okay. So if you look at this document, you have wound complications using xarelto, as compared to a low molecular weight heparin. And then you have, two below it, return to surgery from infection. Do you see that?

A. Yes.

Q. And do you agree with me that if we are looking at PJI's, we should be looking at the differences between xarelto and the low molecular weight heparin for returning to

Page 215

MICHAEL R. REED

surgery for infection; correct?

A. Yes, correct. I just have the caveat that I don't know what timescale this looks at. But it is probably within 30 days, which would be a reasonable thing to look at. (Off the record remarks.)

Q. So would you agree with me that the change from the low molecular weight heparin in the McGovern study to xarelto in the return had no effect; it was not a confounding factor with respect to the infection rates?

A. So based on this study of 12,000 patients, I would say there was no effect on return to surgery from infection.

Q. So would you agree with me that based on this study, that you are an author of, that looking at the date of the McGovern paper, that now we can exclude xarelto as a confounding factor for infection rates?

A. I think that's what this paper says.

THE EXAMINER: Because you nevertheless thought it appropriate to refer to the change in the McGovern paper.

A. Yes, because in our paper, there wasn't a significant difference in infection rates. But there was a signal; that was -- so that's why I put it in. It is safer to be upfront and fair about it.

Page 216

MICHAEL R. REED

BY MR. ASSAAD:

Q. And we had a discussion today about the unidirectional airflow in the operating rooms; correct?

A. Yes.

Q. And you believe that it prevents -- using unidirectional flow prevents peri-prosthetic joint infections?

A. Yes.

Q. Because it reduces the particles in the operating room; correct?

A. Yes.

Q. There is an argument that has been made with respect to critiquing your McGovern article, that laminar flow actually increases peri-prosthetic joint infections. Have you heard that argument before, regarding your article?

A. Yes.

Q. And you are of the opinion that, in fact, that needs to be looked at, because you think the forced air warming has an effect on the laminar unidirectional airflow; correct?

A. Yes. I think it may have an effect on that data.

Q. And actually you have written about that in the book chapter published in 2016; correct?

A. Yes, very likely.

Page 217

MICHAEL R. REED

Q. We have also discussed keeping patients warm during the preoperative and perioperative period; correct?

A. Yes.

Q. And you believe one or the other is fine; correct? Or I could have misunderstood you.

A. Well, it's not -- you haven't misunderstood me, but I think in terms of where the evidence is, I think that's possibly where the evidence is; one or the other is fine. But I would say the best practice now is to do both. And in fact, the NICE guidance draft, which has just come out, will be to do pre-warming and warming during surgery.

Q. But you agree that there's no evidence, scientific evidence, that indicates that keeping a patient warm during surgery and before surgery reduces peri-prosthetic joint infections?

A. So do -- okay. So there's definitely evidence that in colorectal surgery, that keeping people warm reduces their infection rate. And there is evidence from David Leaper's study, who you are going to meet, that pre-warming patients reduces infection rates in their clean surgery. But that is not during the operation. That is before.

I would say there isn't any evidence that doing

Page 218

MICHAEL R. REED

forced air warming during a joint replacement reduces the infection rates. I think that's the -- that's the purpose of the trial.

Q. And the colorectal study you are referring to is the study back in 1996, that I think that counsel was indicating in the 1996 New England Journal of Medicine?

A. It was in the New England Journal of Medicine, yes.

Q. Were you aware that the patients -- the controls were actually cooled in those cases?

A. I was aware of that and I think I put that in the Wood review article.

Q. Okay. Are you aware that Dr. Sessler and Dr. Kurz currently believe that that data would not withstand the current research guidelines today?

MR. GORDON: Object to the form of the question. Assumes facts not in evidence.

A. So their own study, do you mean?

BY MR. ASSAAD:

Q. Yes.

A. I wasn't aware of that.

Q. By the way, going back to the McGovern study, which is exhibit number 8. There is an odds ratio. What is the odds ratio of 3-point -- what does that mean, 3.8 odds ratio?

Page 219

MICHAEL R. REED

THE EXAMINER: Where do I find that?

MR. ASSAAD: Page number Reed 6.

A. It is the risk of something happening, essentially.

BY MR. ASSAAD:

Q. Would it be according -- could it be linked to the relative risk?

A. Yes.

THE EXAMINER: 15 ...

MR. ASSAAD: 42.

BY MR. ASSAAD:

Q. So based on your study in the McGovern, would it be fair to say that the relative risk of getting -- and based on the data, that the relative risk of getting a peri-prosthetic joint infection is 3.8 times greater using a Bair Hugger than using a conductive warming blanket, based on your study?

A. Based on that paper, yes.

THE EXAMINER: What was the figure you put to him?

MR. ASSAAD: 3.8.

BY MR. ASSAAD:

Q. Now, going forward to -- let me go back.

There came a time when you became part of the pilot study that -- it's called the "Reducing implant infection orthopaedics"; correct? The pilot study that

Page 220

MICHAEL R. REED

you were referring to?

A. The RIIO study, is it?

Q. The RIIO study, yes. The RIIO stands for "Reducing implant infection orthopaedics"; and that is under tab number 18. And let's make that exhibit 13. (Exhibit Reed 13 marked for identification.)

Q. Have you seen this document before, this protocol?

A. Yes.

Q. And that is version 1.0, dated September 9, 2016; correct?

A. Yes. I have to say, I am not sure I have seen this version of the document, but I have seen -- I have seen the protocol.

Q. Do you know if there's more than one version?

A. Well, there will be several iterations. I know it is down as version 1.0, but it's probably -- you know, these things evolve over several weeks or months of discussion normally.

Q. Have you been part of authoring this pilot study?

A. I have certainly been involved in the -- in the conference calls about how it's designed.

Q. Were you aware that there was another 1.0 version dated July 5th, 2016?

A. Well, I am sure. I mean, generally there will be lots

Page 221

MICHAEL R. REED

of versions of them.

Q. If you go to exhibit number 4, binder 4. Not in mine. In the big gigantic binders over there.

A. Okay.

THE EXAMINER: Page?

MR. ASSAAD: Page 1609.

A. 1609, is it?

BY MR. ASSAAD:

Q. Yes.

A. Okay.

(Off the record remarks.)

Q. Have you seen this document before?

A. Well, I mean, I have definitely been involved in the evolution of this study.

Q. Were you involved in this project, the pilot study, prior to July 5th, 2016?

A. In terms of discussion about it, yes.

Q. Okay.

And at this time, the funder does not have 3M Healthcare as part of the funding. It has, like, three Xs there under "Funding" on page 1609; correct?

A. Yes, correct. It is just the Healthcare Infection Society.

Q. Do you know when 3M Healthcare decided to become

Page 222

1 MICHAEL R. REED
 2 involved in this pilot study?
 3 A. A little earlier than this; but I don't think they have
 4 signed contracts. I'm not aware they have signed
 5 contracts. So normally these things actually evolve
 6 over several months.
 7 So were they discussing it in July? I think there
 8 probably was an expression of interest and
 9 an understanding that 3M may fund it, I believe.
 10 Q. Do you know Dr. Mark Harper?
 11 A. Yes.
 12 Q. How do you know Dr. Mark Harper?
 13 A. Well, we sit on the NICE guidance committee together.
 14 I run an infection prevention meeting in the North,
 15 which he spoke at about a month ago. So I have met him
 16 a few -- well, I would say three times.
 17 Q. Do you know that he is on the 3M advisory panel,
 18 scientific advisory panel?
 19 A. No, I didn't know that.
 20 Q. Do you know he got paid by 3M?
 21 MR. GORDON: Object to the form of the question.
 22 A. No.
 23 THE EXAMINER: What for?
 24 BY MR. ASSAAD:
 25 Q. For his consulting.

Page 224

1 MICHAEL R. REED
 2 A. So I have been involved in the design, if you like, of
 3 it; and I will be a recruiting center for it. Our trust
 4 will recruit patients, I think. That depends a little
 5 bit on whether my colleagues are willing to do it. But
 6 I mean, this is a study that I have been wanting to do
 7 for some time.
 8 Q. Since you published the McGovern study; correct?
 9 A. Since before that. 2009 is when I asked Scott Augustine
 10 to fund it. We didn't ask 3M at that point.
 11 Q. And how much is the study going to cost, approximately,
 12 this patient study? Is there an estimate?
 13 A. I think -- I have got the figure on my CV. So this is
 14 a pilot study, so it is not the whole study. But
 15 I think the -- I think 3M and the infection --
 16 Healthcare Infection Society are putting in, was it
 17 117,000 I saw on my CV?
 18 Q. Yes. And are you getting compensated for your time
 19 involved in this study?
 20 A. No.
 21 Q. Do you have a contact at 3M that you are dealing with,
 22 regarding this study?
 23 A. Regarding this study, no. I have got no involvement
 24 with 3M personally, with this study. I do have
 25 involvement with a different branch of 3M over my other

Page 223

1 MICHAEL R. REED
 2 A. No. He may have been the link between 3M and the study,
 3 I suppose. He probably was.
 4 Q. I take it the null hypothesis in this study is that
 5 there is no difference between forced air warming and
 6 resistive fabric warming; correct?
 7 A. Yes.
 8 Q. What is the hypothesis?
 9 A. So we are just trying to tell if there is a difference
 10 between the two. And we will decide on numbers, based
 11 on the first 1,000 patients that we get in; it will give
 12 us a feel for the infection rates and then we will be
 13 aiming to show a difference or not between the two.
 14 Q. But what is the working hypothesis, though? There has
 15 to be a working hypothesis. Is one better than the
 16 other?
 17 A. I am not sure how the stats are structured, to be
 18 honest; whether it is an equivalent study or
 19 a superiority study.
 20 Q. I think it is a superiority study. So it has to ...
 21 A. Well, I imagine suggesting then that there is
 22 a difference, that forced air has a higher infection
 23 rate. But I can't remember the detail of that, I am
 24 afraid. Unfortunately it's not my study.
 25 Q. What is your involvement in the study going to be?

Page 225

1 MICHAEL R. REED
 2 randomized trial that I am doing.
 3 Q. Were you aware that other experts such as -- such as
 4 Dr. Sessler has also advised 3M over the years back?
 5 MR. GORDON: Object to the form of the question.
 6 BY MR. ASSAAD:
 7 Q. If you go to page ...
 8 Sorry.
 9 (Off the record remarks.)
 10 Q. Page Reed 172, 15 of 22 of the pilot. And this is the
 11 pilot study with your name on it; is that correct?
 12 A. Yes.
 13 Q. Okay.
 14 If you look at the fourth line down, under "Warming
 15 method and temperature monitoring" under 8. It says:
 16 "Both forced air warming and resistive fabric
 17 warming are established and licensed for use in the U.K.
 18 and are equally effective at preventing inadvertent
 19 perioperative hypothermia."
 20 Did I read that correctly?
 21 A. I can't see where you are reading it, but what you
 22 said --
 23 Q. Under "Warming method" --
 24 THE EXAMINER: Right down at the bottom of the page.
 25 BY MR. ASSAAD:

Page 226

MICHAEL R. REED

Q. The third line up from the bottom.

A. Yes. Yes.

"... are established and licensed for use in the U.K. and are equally effective at preventing inadvertent perioperative hypothermia."

Yes. I think that is a reasonable statement.

THE EXAMINER: So the primary function, they are equivalent.

A. In terms of warming, yes, I think that is a fair summary. I think even that is debated, but yes.

BY MR. ASSAAD:

Q. Mr. Reed, you stand by your studies; correct?

A. Yes.

Q. And even though Mr. Albrecht and Dr. Augustine were funding the studies involved, they did not influence the data or the results that you have concluded; correct?

A. Yes. So just to be clear, there was no funding for any of these studies apart from the very first one, which was the one actually that didn't show any difference.

But yes, I do stand by them, yes.

MR. ASSAAD: All right. At this time, under the Federal Rules of Evidence, I am going to offer him as an expert and the stuff he has testified in, with respect to orthopaedic surgery, peri-prosthetic joint infections and the causation of peri-prosthetic joint infections.

Page 227

MICHAEL R. REED

And after that, I have no further questions.

THE EXAMINER: I am sorry, you are going to have to say that again.

MR. ASSAAD: I am offering him as an expert in the testimony he has given to his studies, with respect to orthopaedic surgery, general causation on peri-prosthetic joint infections and general peri-prosthetic joint infections under the Federal Rules of Evidence.

THE EXAMINER: I don't know what you mean by "offering him as an expert". However, he is not here specifically under the terms of the U.K. order to give expert evidence, on the basis that both parties have their own experts in the United States.

Now, if you want to try and change this into something different in the U.S.A., that is a matter between the parties and the judge but I want to make it crystal clear that he has not been giving evidence today in this room as an expert. Okay?

Now, Mr. Gordon, it seems to me on the timescale, you have about 20 seconds left for re-examination.

MR. GORDON: I thought it was more like 40.

FURTHER EXAMINATION BY MR. GORDON:

Q. Mr. Reed, when counsel asked you about the McGovern studies showing an odds ratio of 3.8, and he asked you

Page 228

MICHAEL R. REED

to agree with him, or whatever the exact words were, I can't remember. But essentially that using forced air warming was 3.8, and it increased the rate of infection 3.8 times over the other warming modality and you said "based on that paper".

Two questions.

First of all, why in the paper did you say:

"This study does not establish a causal basis for this association."

MR. ASSAAD: Objection to form.

THE EXAMINER: You may answer.

A. Because it doesn't. It doesn't establish causation, our paper. The -- yes, okay.

BY MR. GORDON:

Q. So what did you -- when you said "based on that paper", I mean, what was it that you were saying?

A. So as I said right at the start, right at the start of the proceedings, I said I wanted to mention something about that paper.

And -- in that we -- there was some very up to date data which I thought was in it. It does not actually change the material effect of the paper. You know, the conclusions are still the same.

But that final data that we got in, for some reason,

Page 229

MICHAEL R. REED

did not get into the final paper. It might -- it did change the odds ratios very slightly. That's the reason that I mention it.

So it might not be 3.9. It was probably 3.8 or something like that. But I think it is somewhere in here. We could look it up.

Q. But regardless of whether it's 3.8 or 3.9 or ...

What does it mean that there is -- that the study does not establish a causal basis?

MR. ASSAAD: Objection. I think his time is up.

THE EXAMINER: I think I will allow you to answer this question and then that's it.

A. So what we have shown is association and not causation.

We made that pretty clear in the paper.

THE EXAMINER: Okay.

MR. GORDON: Thank you.

THE EXAMINER: Thank you very much.

MR. ASSAAD: Thank you.

THE EXAMINER: That concludes your examination, Mr. Reed. Thank you very much indeed.

THE VIDEOGRAPHER: This is the end of the deposition of Michael Reed. We are going off the record at 5:53.

(5:53 p.m.)

(Whereupon the deposition concluded.)

Page 230

MICHAEL R. REED

CERTIFICATE OF DEPONENT

I, MICHAEL R. REED, hereby certify that I have read the foregoing pages, numbered 1 through 232, of my deposition of testimony taken in these proceedings on Sunday, December 4, 2016, and, with the exception of the changes listed on the next page and/or corrections, if any, find them to be a true and accurate transcription thereof.

Signed:
Name: MICHAEL R. REED
Date:

Page 231

MICHAEL R. REED
CERTIFICATE OF COURT REPORTER

I, ROSE HELEN CLAIRE KAY, an Accredited LiveNote Reporter of London, England, hereby certify that the testimony of the witness MICHAEL R. REED in the foregoing transcript, numbered pages 1 through 232, taken on Sunday, December 4, 2016 was recorded by me in machine shorthand and was thereafter transcribed by me; and that the foregoing transcript is a true and accurate verbatim record of the said testimony.

I further certify that I am not a relative, employee, counsel or financially involved with any of the parties to the within cause, nor am I an employee or relative of any counsel for the parties, nor am I in any way interested in the outcome of the within cause.

Signed:
ROSE HELEN CLAIRE KAY
Dated: December 7, 2016

Page 232

MICHAEL R. REED

ERRATA

Deposition of MICHAEL R. REED

Page/Line No.	Description	Reason for change
---------------	-------------	-------------------

Signed:
Name: MICHAEL R. REED
Date:

A				
AANA (1) 22:18 ability (1) 205:17 able (5) 79:23 92:14 153:3 188:9 189:19 abstract (8) 30:7 33:11 86:23 130:14 131:14 132:4,9 143:23 abstracts (2) 165:15 166:2 Academy (2) 134:22 174:11 accept (6) 38:8 107:22 111:14 139:20 143:25 157:18 acceptable (1) 56:5 accepted (17) 23:12 31:13 32:3 107:21 136:9,17,17 139:16,21 142:16 143:23 144:3 157:20 184:20 185:3 187:9 193:3 access (1) 180:20 accompanying (1) 55:8 Accredited (1) 231:4 accurate (8) 54:3,7,8 61:22 73:6 181:4 230:7 231:7 accuse (1) 70:20 acknowledge (1) 17:18 action (2) 69:2 114:14 active (1) 86:7 activities (1) 141:18 actual (3) 53:4 56:25 184:21 ad (2) 29:20 170:2 adapting (1) 7:24 add (4) 125:4 128:13 137:19	205:24 added (2) 52:15 206:18 adding (2) 83:17 116:21 addition (2) 83:24 92:8 additional (5) 11:5 38:16 56:24 137:19 205:10 address (6) 7:13 42:5 115:24 124:7 125:3 133:3 adequately (1) 16:4 administration (2) 5:7 212:21 administrative (1) 11:5 admissibility (1) 15:18 admission (1) 87:23 admitted (1) 170:5 adopted (1) 108:25 advance (3) 13:19 18:6 71:18 advanced (1) 13:7 advantage (4) 94:9 98:5 120:23 125:23 advantages (1) 118:6 advised (2) 135:12 225:4 advisers (1) 67:12 advisory (2) 222:17,18 advocating (1) 66:19 affect (3) 43:22 44:6 157:21 affiliated (1) 10:22 afraid (5) 98:18 127:22 149:2 199:20 223:24 afternoon (1) 7:18 aged (1) 58:19 Agency (2)	67:2,8 agenda (6) 133:15,18 134:6,9 137:24 141:18 agent (2) 185:20 186:2 ago (9) 8:4 13:23 139:5 157:12 162:4 164:9 168:19 189:3 222:15 agree (32) 71:13 79:22 119:6,12 123:12 137:5 150:23 175:12 178:16,17 183:16 183:19 184:13,15 186:22 192:23 204:18,25 205:23 206:10 208:7,11,24 209:3 210:2,8 214:14,23 215:7,14 217:14 228:2 agreed (1) 18:23 agreeing (1) 162:5 Ah (3) 52:6 128:24 156:17 ahead (2) 113:4 146:10 aiming (1) 223:13 air (47) 1:5 6:10 21:18 23:5 23:23 26:16 27:7,12 27:17,23 31:15 33:5 33:8 36:5 49:25 73:23 78:11 122:2 123:11,13 125:10 125:19 129:6 132:8 135:6 142:18 154:3 154:4 157:21,22 158:6 159:23 175:16,24 199:17 204:6 206:12,18 209:7,10 211:7 216:19 218:2 223:5 223:22 225:16 228:3 airborne (1) 208:7 airflow (9) 25:23 33:2 79:5 191:25 198:7 206:14 207:10	216:4,20 al (3) 34:12 126:23 128:12 albeit (2) 129:13 172:11 Albrecht (29) 41:15 43:25 49:6 53:5 53:7 122:21 123:17 123:20 124:2 126:19,25 127:20 131:21 133:10 138:3,25 144:14 146:3,19 147:6,8 148:14,22 156:3,6 157:12 201:8 204:10 226:14 Albrecht's (1) 138:23 alcohol (1) 77:8 alert (1) 151:20 Allen (2) 2:8 7:6 allow (4) 42:13,16 43:11 229:12 allowed (2) 87:5 145:15 allows (1) 188:7 alluding (1) 114:3 alternative (2) 36:5 189:10 American (5) 134:22 150:2 174:11 213:9,10 amount (4) 62:3 174:17 181:7 208:21 amputations (1) 181:25 Amsterdam (1) 127:20 analysis (9) 36:12 37:21 44:16 51:23 53:4 106:24 118:23 203:3,13 analyzed (2) 53:16 214:5 and/or (1) 230:7 Andrew (1) 192:5 anesthesia (2)	22:20,21 Anesthesiologists (1) 150:2 anesthesiology (1) 145:8 annum (1) 63:25 anonymously (1) 180:4 answer (27) 34:4 35:7 38:3 39:17 43:12,16 45:13 53:9 55:14 62:13,24 74:12,14,22 103:13 119:11 136:24 143:9 155:11 162:17 163:3,11,20 191:12 209:4 228:12 229:12 answered (1) 39:11 answers (2) 191:18 194:24 antibiotic (27) 82:11 84:10,22 85:3 85:21 89:11,18 90:11,23 91:3,14 98:11,14 102:3,4 103:5 106:9 110:16 185:15,16 204:12 204:16,19,23 205:2 205:17 206:3 antibiotics (20) 92:8 97:25 99:15,18 99:20 102:16 103:10 105:7 108:13 110:21 179:15 184:9 185:9 185:11 188:9 189:16 204:5,22 205:23 206:6 anticipate (1) 143:7 anxiety (2) 26:14 118:4 anxious (1) 153:22 anybody (1) 72:21 anyway (2) 18:8 24:3 anyways (1) 145:9 apart (6) 39:20 61:20 162:7 178:14 210:22

226:18	85:3	73:15,24 74:11,19	assistant (1)	96:2,24 99:5 144:13
apologize (5)	arthroplasty (4)	74:22 75:3 76:10	186:9	Augustine (43)
13:19 20:6 42:20 92:5	37:11 196:17 198:15	77:13,16,20,23,25	assisting (1)	26:8 27:3,8 28:2,4,9
133:4	212:23	79:22 80:3,8 81:8	71:11	28:13 31:9 33:7
APPEARANCES (2)	article (17)	81:14,18 82:8 86:25	assists (2)	34:19,21,23 36:2
2:4 3:3	5:5,6 79:18 100:23	87:13 99:17 100:12	73:6,9	38:12,25 39:5 40:4
appears (3)	111:9 116:19 145:8	100:15,17 101:18	associated (1)	40:4,21,21 41:15
61:9 146:18 204:23	180:2,12 191:20	103:11 105:9,18	85:20	55:7,9,10 123:22
appetite (1)	195:7 211:14 212:7	107:4,9 108:5,14	association (10)	124:5,7 131:22,22
157:5	212:10 216:13,16	116:23 119:10	6:20 11:15,16 85:15	133:12,12 134:11
apples (2)	218:12	129:24 130:11,16	110:3 174:5 182:6	135:6 141:13
108:11,12	articles (6)	130:23 131:2,4,6,8	210:19 228:10	144:15 146:21
application (4)	165:19 166:17 176:2	133:20,25 136:23	229:14	148:15,23 157:2,2
73:13,21 74:3,5	177:11 192:18	137:13,25 138:6,8	assume (7)	160:15 224:9
applied (1)	198:21	138:10,21 139:3	40:8,11 41:2 144:21	226:14
73:18	ASA (8)	145:12 155:4,8,9	163:3 208:21	Augustines (1)
applies (1)	149:5,23,23 150:4,5	160:25 161:2,20	209:18	148:24
56:9	151:2,5,19	162:19 163:23	assumes (4)	aureus (4)
apply (2)	ascertain (1)	164:2,4,24 166:15	55:12 103:12 138:22	113:25 114:3,10
72:25 142:23	31:23	167:6,10,16 168:24	218:16	120:8
appoint (1)	ascribe (2)	170:18 171:8,21	assuming (1)	auspices (1)
69:3	35:19 181:13	175:22 176:10,23	141:15	173:6
appointed (3)	asked (16)	176:25 179:14	assumption (1)	authentic (3)
7:6 11:3 69:16	34:18 39:19 52:6	182:22 183:4,15	139:15	14:11 15:14 18:21
appreciate (2)	64:19 101:23	184:23 185:2	assure (1)	authenticity (2)
42:17 96:8	131:23 132:3 143:8	186:16,18,21	24:4	17:2 54:7
appropriate (2)	143:16 158:25	187:16 188:24	attached (2)	author (18)
7:19 215:20	163:4 190:24 214:3	190:4 191:19	132:23 133:6	21:23 22:8,10,13 23:3
approximately (3)	224:9 227:24,25	193:16 195:3,9	attachment (2)	23:15 24:9,11,13
8:5 165:10 224:11	asking (14)	196:5,7,10,11,22,24	132:7 133:5	31:6 107:13 128:7,9
April (5)	13:10 34:17 36:2	197:2,3,10,14,17,18	attack (1)	131:17,25 145:9
23:12 50:6 97:10	76:12 94:4 109:24	198:25 199:4,8	149:14	196:14 215:15
102:22,23	131:11 188:22	200:5,7,10,15,17	attacks (1)	authored (3)
Aquacel (1)	190:16 191:5 201:4	201:19 202:17	115:21	147:5 195:4,6
111:21	205:5,13 210:9	203:16,18,20 205:7	attempt (1)	authoring (1)
Arch (1)	asks (2)	205:12,20,22 206:5	32:8	220:20
17:18	143:4,17	207:18 209:12,19	attempted (1)	authors (7)
area (7)	aspect (1)	209:25 210:12,14	62:25	76:7 126:18,25
22:21 37:25 109:14	34:2	211:9,12 212:4,7,9	attending (4)	127:19 145:2,4
119:8 180:5 194:21	aspects (1)	213:16,18 214:8	172:17,18 173:14,17	213:23
195:18	129:20	216:2 218:19 219:3	attention (6)	authorship (2)
areas (1)	Assaad (214)	219:5,10,11,20,21	24:6 74:25 122:15	64:21 144:22
37:18	3:8 4:8 6:25,25 13:25	221:7,9 222:24	124:22 130:5	autonomous (1)
argument (2)	14:5,24 15:2,7	225:6,25 226:11,21	205:11	172:12
216:12,15	16:17,19 18:9,19,25	227:5 228:11	attorneys (8)	available (3)
argumentative (1)	19:4,8 21:3 34:3	229:11,19	65:4 77:19 85:19	154:3,5,18
119:10	35:5 37:17 38:4	assassin (1)	161:3,7,11,13,17	Avenue (2)
arising (1)	39:11 40:8 45:12,25	151:24	attractive (1)	3:12 6:19
46:5	46:4 48:15 49:5,19	assess (4)	140:2	average (1)
Arizant (6)	52:20 53:8,18 54:3	78:18 104:2,3 153:9	audience (1)	193:9
2:23 6:24 151:25	54:5 55:12 56:3,7	assessment (1)	143:4	avoidance (1)
152:3 161:18	56:10 58:5 61:11,13	78:20	audit (5)	20:9
199:14	62:11,23 64:18,24	assign (1)	113:2,3,5,11,13	avoiding (5)
arranged (2)	65:5,8 66:11,16	36:4	August (12)	12:4,6,11,14,15
28:8,12	69:5,19,25 70:9,13	assist (1)	22:2 23:11 51:7 83:6	award (13)
arthroplasties (1)	70:18,20 72:10 73:2	173:11	88:23 89:7 93:18,20	71:8,10 72:19,22,24

73:2,13,13 74:3,16 74:21 177:4,5 awarded (3) 72:24 168:17 170:2 awards (4) 73:18 176:17,19 177:3 aware (23) 63:14 117:3 128:3,6 130:8 135:2 147:14 158:8 164:19 192:15 201:20,22 201:23,24 204:10 204:15 218:9,11,13 218:21 220:23 222:4 225:3 AZ (1) 61:9	21:20 27:13 28:19 32:24 35:3 60:8,17 84:23 183:16,20 184:2,5,8,16 185:13 186:2,23 188:4 189:17 193:24 194:13,16 206:7 207:20,22 208:3,4 208:22 209:14,22 210:3,16 214:10 bacterial (1) 31:22 Bair (61) 1:5 6:10 47:6,10,19 48:19 50:12,16,23 51:12 63:18 79:3 80:16 83:21 88:11 88:14,21 90:17,18 90:22,25 91:2,8,15 91:16,19,24 93:24 97:8,13,18 98:13,14 99:3,11,14,14,20 102:14,15 103:4 105:6 106:9,16 108:11 114:19,23 115:2,3 119:22 154:6,7,11,15,20 161:4 186:13 206:13 207:11 208:24 219:16 Baker (2) 6:5,14 balance (1) 89:23 base (2) 111:5 194:4 based (27) 31:23 67:3 69:12 75:19 81:19 82:14 86:25 87:13 96:8 102:13 117:20 123:18 171:12 176:17 178:20 206:10,11 208:24 215:12,14 219:12 219:13,17,18 223:10 228:6,16 basic (1) 212:24 basically (3) 32:4 66:19 185:19 basis (14) 22:17 42:14 77:21 78:25 97:4 108:15 110:2,14 111:12 204:21 205:15	227:13 228:9 229:10 Bates (6) 5:2,5 55:6 76:11 155:14 156:7 Bayer (3) 151:25 152:2,7 Bearing (1) 103:23 beast (1) 37:3 bed (1) 33:12 began (2) 63:17 153:21 beginning (12) 46:3 84:2 91:24 92:3 95:19 96:4,11 113:6 132:22 153:20 166:23 183:12 begins (2) 43:9 110:13 behalf (4) 6:23,25 7:2 147:9 belabor (1) 140:24 Belani (11) 23:15,18 70:5 145:25 146:2 196:12,14,19 196:21 197:9 208:25 believe (9) 17:23 139:21 155:21 208:10 213:19 216:6 217:5 218:14 222:9 Bench (1) 6:12 benefit (4) 114:20 115:5 118:3 151:14 best (7) 32:20 36:10 48:21 127:14 149:17 177:6 217:10 bet (1) 19:9 betadine (1) 77:14 better (10) 11:25 19:24 31:25 35:25 36:12 37:9 41:15 133:14 139:14 223:15 beyond (5) 83:8,8 88:13 90:6,6	BF (1) 59:7 BG (1) 60:11 BHS (2) 135:17,25 bid (1) 69:3 big (17) 14:15 64:4 85:14,16 85:21 108:17,22,23 149:10 151:8 153:4 158:5 159:11 164:19 175:19 178:12 221:4 bigger (2) 108:22 200:25 billion (1) 208:12 binder (7) 4:17,18,19,22 14:8 146:6 221:3 binders (3) 15:15 16:6 221:4 biofilm (9) 184:7,8,11 185:7,13 188:3,6,8 189:16 bit (12) 18:2 27:15 33:16 42:21 43:10 48:17 52:3 85:22 91:17 117:18 211:2 224:5 black (1) 71:3 BLACKWELL (1) 2:21 blank (2) 199:24 200:12 blanket (1) 219:17 bleeding (6) 94:17,21,22,24 115:21 118:4 blister (1) 112:12 blistering (1) 112:13 blood (1) 95:2 bloodstream (1) 189:7 blue (2) 72:25 109:8 blues (1) 111:8 Blvd (1)	3:7 BMI (1) 149:6 boards (3) 168:15 169:2,4 Bob (3) 131:16 144:21 145:9 body (5) 45:8 142:5 173:17 181:8 184:10 Bone (4) 180:19,24 213:7,10 book (3) 177:12,19 216:23 book-ends (1) 47:2 border (1) 9:6 borrow (1) 100:2 bottom (17) 23:13 26:7 77:5 112:23,24 122:20 134:11 136:19 139:23 142:4 144:20 148:21 150:17 157:4 197:19 225:24 226:2 bound (1) 17:14 Bournemouth (1) 136:4 box (7) 76:16 112:24 117:16 117:18 118:18 121:14 149:15 boxes (2) 135:18 137:2 branch (1) 224:25 breadth (1) 171:12 break (6) 95:17 122:10 159:14 160:22 163:6 183:10 Brent (3) 133:12 134:11 157:2 brief (2) 121:20,21 briefly (8) 23:2,21 84:21 160:19 166:21 167:4 195:21 214:3 bring (3)
---	--	---	--	--

24:5,6 195:7 Britain (2) 174:20,22 British (7) 11:16 30:15,25 31:3 33:24 174:4,5 broad (1) 193:5 broadbrush (1) 45:7 broadier (1) 137:21 broadly (1) 44:15 broken (1) 61:2 brought (1) 144:24 bubble (4) 145:7 153:20,22 198:7 bubbles (2) 206:22,25 bug (2) 114:17 132:15 bugs (1) 57:18 build-up (1) 21:20 bumbling (1) 143:9 bunch (2) 70:4 80:18 bundle (5) 17:12 18:23 100:8,14 128:25 burden (1) 144:25 BURKE (1) 2:21 business (1) 69:15 busy (1) 148:11	called (7) 10:4,5,6 111:21 150:14 172:5 219:24 calls (4) 73:24 133:20 145:12 220:22 campaign (1) 85:21 Canada (1) 2:17 canopy (1) 207:8 carbon (2) 123:21 133:11 care (5) 11:22 87:23 112:20 187:17,19 career (1) 168:19 careful (1) 141:17 carried (1) 210:7 carry (4) 17:3 130:22 131:9 208:4 carrying (1) 208:17 case (7) 39:14 63:12,12 69:15 115:8 164:21 197:10 cases (8) 56:23 63:2,3 169:21 189:18,19 195:13 218:10 catastrophic (1) 181:21 category (5) 30:23 61:9,21 62:18 70:11 causal (4) 110:2,14 228:9 229:10 causation (5) 182:24 226:25 227:7 228:13 229:14 cause (15) 84:23 95:2 118:23 182:4,5 183:16,20 184:6 194:13,16 207:21 210:3 211:6 231:10,11 caused (2) 189:5 207:10	caveat (3) 60:21,23 215:3 caveats (3) 82:14,24 210:22 CC (2) 144:14 148:22 CCed (2) 134:12 146:20 CD (1) 183:5 cease (1) 122:5 cefuroxime (11) 82:12 83:5,11,20 85:9 85:13 86:2,15 87:21 88:7,12 celebrity (4) 27:15 28:17,20 29:23 cell (2) 57:16 58:8 cells (1) 208:12 cement (1) 84:20 center (2) 201:2 224:3 centers (1) 203:23 certain (9) 37:25 53:13 76:20 111:19 116:3 169:10 180:17,18 195:13 certainly (25) 17:21 33:3 51:14 56:23 79:15 90:21 95:6 115:8 116:14 116:16 132:25 153:14,18 160:6 175:17 179:8 181:2 181:6 187:13 189:2 207:25 208:9 212:12 214:17 220:21 certainty (2) 113:8,22 CERTIFICATE (2) 230:3 231:2 certify (3) 230:5 231:4,9 cetera (3) 25:12 169:22,22 CFU (1) 207:19 CFUs (1) 207:24	CFW (2) 125:7,16 chain (12) 5:2 122:17,18 124:19 129:22 132:23 133:5,8 144:12 146:17 148:19 185:17 chair (2) 11:14 68:6 challenge (1) 7:24 challenges (1) 18:22 CHAMBERS (1) 2:11 chance (3) 63:13 152:25 210:4 change (30) 44:21 73:23 74:25 85:13 86:6 89:21 91:23 92:8,13,20 93:7 95:4,11 96:10 109:17 111:15 113:9 120:23 183:5 204:5,18 205:2,23 210:21 215:7,20 227:15 228:23 229:3 232:5 changed (16) 82:25 84:17 88:20 89:20 92:9,21,22 102:9 111:8,16,19 111:20 113:4,8 210:20 214:4 changes (16) 67:24 71:16,25 78:23 84:9 89:17 109:18 110:16,18 111:2,4 141:3 180:8 210:22 211:4 230:6 changing (5) 74:17 109:13 182:20 206:6 211:16 chapter (1) 216:24 chapters (2) 177:12,19 character (1) 28:21 charge (1) 173:19 charged (1) 85:24 charity (6) 160:5,7,7,9,9,10	Charlson (5) 150:14 152:20,21 153:4,8 chart (10) 4:20 48:4,22 49:17 73:7 97:8 100:6 102:11 120:16 125:5 charts/notes (1) 149:6 chase (2) 42:18 119:6 cheaper (1) 36:22 check (2) 63:12 134:18 checked (1) 79:2 chest (2) 87:22 149:14 chief (1) 158:15 chlorhexidine (1) 118:11 chlorhexidine-alco... 77:9 choice (3) 131:15 145:9 206:3 choose (1) 63:23 chose (1) 111:4 chosen (1) 159:15 Chris (1) 144:23 Christopher (1) 123:22 chronological (2) 166:24 167:18 circle (1) 132:12 cite (2) 92:14 192:18 cited (4) 166:17 176:2 194:5 199:23 claimants (1) 161:14 CLAIRE (2) 231:4,23 clarification (2) 53:18,22 clarify (1) 81:22 classification (1)
--	--	---	---	---

61:3 clean (7) 48:25 49:9 76:14 100:6,17 189:14 217:23 cleaning (1) 63:7 clear (32) 43:20 53:22 58:25 67:24 76:14 78:21 81:22 82:13,20 86:25 87:13 106:19 107:4 119:15 127:2 128:18 132:5 138:11 140:16 145:7 152:4 162:22 163:15 166:24 173:20 190:21 191:13 198:12 212:17 226:17 227:18 229:15 clearly (5) 159:6 162:6 193:6 194:22 205:19 click (1) 165:5 client (1) 17:14 clinical (26) 23:25 24:2,21 25:5,6 25:7 36:3,8,9,19 37:15 38:13 39:2 41:14,16 42:25 43:21 44:15 75:16 82:19 107:23 128:11 142:23 143:24 197:25 198:8 clinicians (1) 128:11 close (4) 87:20 205:5 207:5,5 closed (2) 121:18,22 closely (1) 146:23 closer (1) 116:12 Clostridium (6) 85:15,22,24 86:12,16 87:19 closure (1) 121:24 clots (1) 12:2 clue (1)	145:6 co-author (1) 96:19 co-authors (2) 53:2 146:3 co-morbidities (2) 56:19 194:11 Coast (1) 9:8 coder (1) 62:5 coders (1) 149:12 codes (1) 149:11 coding (4) 52:14 58:2 63:6 109:2 coding/billing (1) 149:3 coincide (2) 80:18 97:24 coincides (2) 105:5 106:8 cold (3) 115:18,19 116:15 collate (1) 67:3 collated (1) 203:23 colleague (1) 211:20 colleagues (2) 180:14 224:5 collect (6) 45:2,11,14 46:9,23 149:16 collected (10) 44:18,19,24,25 45:22 51:17 56:25 149:11 150:6,7 collecting (4) 46:11,22 67:4 151:18 collections (1) 94:25 college (5) 168:18,22 170:12,23 171:6 colleges (2) 170:13,22 colony (5) 207:16,19,25 208:17 208:20 color (3) 109:2 111:8 210:25 colorectal (2) 217:19 218:5	colorful (1) 28:21 Colour (1) 4:20 column (10) 54:20 56:13 57:9 58:16 59:7 60:11,11 76:16 84:10 101:19 columns (1) 55:25 combination (2) 89:16 90:14 combined (1) 66:4 come (25) 20:24 26:3 28:5 35:24 46:10 57:4 62:15 72:24,25 78:3,17,18 113:23 114:7 115:11 118:22 122:5 132:16 159:4 159:5 188:11 189:3 201:8 205:11 217:12 comes (2) 13:2 187:8 comfortable (1) 145:3 coming (7) 26:7 28:9 117:7 136:21 175:7,20 206:19 commencing (2) 6:7 63:18 comment (21) 135:18,19,20 136:19 137:3,10,18 138:11 138:23 139:18,24 140:3,6,18,22,22 141:4,16 142:3,8 146:8 commented (5) 136:25 138:17,19,20 141:11 commenting (1) 147:23 comments (12) 123:4 125:4 136:20 138:14,17 139:7,10 139:12,12,20 140:11,12 committee (13) 11:15,18,23 12:4,14 12:20 13:4,5 68:3,6 70:3,14 222:13 committees (1)	11:17 common (6) 60:8 77:2 98:12 111:13 142:22 143:18 commonly (3) 14:12 187:9 189:8 communicated (1) 34:21 communications (8) 40:20,21 41:22,25 42:2,3 147:9,11 community (3) 9:19 22:15,16 companies (4) 40:5 71:6 152:2 154:2 company (2) 2:23 135:7 comparator (1) 106:4 compare (7) 103:14,15 108:11,17 108:22 153:4 209:6 compared (10) 80:16 102:24 103:4 103:18 104:24 126:8 169:8 178:13 211:18 214:19 comparing (2) 27:7 159:8 comparison (5) 42:24 97:12 140:8 172:22 212:21 compensated (1) 224:18 compiled (1) 62:20 complain (1) 124:25 complete (3) 21:6 46:19 150:24 completed (1) 168:5 completely (3) 162:3,9 171:16 compliance (1) 94:10 complicated (1) 129:10 complication (5) 119:14 181:20 182:19 182:21 212:15 complications (8) 5:7 56:18 94:15 115:20 212:20 213:3 214:6,19	component (3) 25:23 42:25 44:15 components (1) 25:15 compulsory (1) 117:8 computer (1) 56:25 computerized (1) 52:5 computers (1) 52:13 conceived (1) 25:14 concept (1) 129:14 concern (5) 111:5 148:8 152:7 157:7,14 concerned (3) 79:21 148:6 149:20 concerning (2) 108:3 147:16 concerns (2) 122:23 196:4 concluded (2) 226:16 229:25 concludes (1) 229:20 conclusion (3) 35:25 43:22 44:7 conclusions (3) 87:8 99:25 228:24 conditioning (1) 122:2 conditions (1) 187:19 conduct (1) 16:22 conductive (13) 27:8 50:2 125:20 142:19 153:25 154:16,18 158:6 159:23 202:20 204:7 209:7 219:16 conference (3) 26:12 135:5 220:22 confess (2) 73:4 213:4 confined (1) 80:12 confirm (1) 207:13 confirmed (1) 60:19 confounded (1)
---	---	--	--	--

110:6 confounding (3) 205:3 215:10,17 confused (3) 48:17 137:16 198:11 confusing (2) 33:16 170:25 confusion (1) 92:6 conglomerate (1) 120:20 connect (1) 28:4 connected (1) 32:8 consciousness (2) 157:8,15 consensus (10) 175:4,8,9,15 176:5,7 176:11,15 182:11 185:4 consider (3) 139:2 182:8,23 considered (2) 39:16 205:3 constantly (1) 148:17 constraints (1) 172:11 constructed (1) 36:13 consultant (15) 8:3 10:24 27:3 75:8 158:19 168:14,16 171:23 172:2,4,7,9 172:10,24 173:23 consultants (1) 173:21 consulting (1) 222:25 consume (1) 155:18 CONT'D (1) 3:3 contact (3) 161:23 162:4 224:21 contacted (1) 26:13 contains (1) 82:24 contaminants (1) 208:7 contaminate (3) 109:10 206:4 207:11 contamination (5) 27:23 31:22 205:24	209:9,13 contended (1) 76:18 contentious (1) 157:19 contest (1) 163:7 context (2) 128:11 137:21 continue (4) 42:14,16 92:19 188:7 continued (4) 91:10 95:2 202:15,24 continues (1) 137:4 continuously (1) 20:14 continuum (1) 107:21 contracts (2) 222:4,5 Contrary (1) 183:23 contribute (1) 175:15 contributor (1) 208:8 control (12) 39:23 69:17 70:3,11 71:16 74:18 80:19 110:6,18 119:19 158:4 180:12 controlled (1) 123:9 controls (1) 218:9 convection (2) 206:12,17 convention (1) 24:13 conversation (4) 26:22 134:2 141:7 150:14 conversations (2) 162:12,13 cooled (1) 218:10 coordinator (1) 71:4 COPD (2) 150:23 151:17 cope (1) 20:23 copied (4) 124:5 130:7 131:2 133:3	copies (2) 81:6 100:6 copy (22) 17:6 23:9 48:25 49:9 49:13 58:24 72:6 79:23 80:2,3,5,8 100:12,17,24 101:22 123:21 128:20 133:11 165:4,9 199:24 copyright (1) 23:13 Corey (2) 2:23 6:23 corner (1) 19:23 corporate (1) 141:18 correct (126) 7:25 25:8 40:18 44:17 45:10 47:7,11,16,21 50:7 64:2 81:12 83:5,6,25 85:3 89:12 90:15 91:4 94:18 97:15 103:10 105:11 108:13 117:14 120:25 136:13 141:15 161:5,6 162:10 165:11 169:2 171:9 171:10 173:22 174:12,13 175:23 175:25 176:18 177:13,15 178:8,9 178:10,11,13 179:16,17,19 180:15 181:14,18 181:21 183:17,21 183:22,24 184:7,18 185:5,9 186:2,5,24 187:2,6,17,18,20,24 188:3 190:7 191:25 192:16,19,21 193:18,21,24 194:7 194:14,17,18 196:12,14 197:22 198:9,17,18,19,20 202:6,25 205:25 206:15,20 207:22 208:8,18,19 209:15 209:23 211:16 213:8 214:10,11,16 215:2,3 216:4,10,21 216:24 217:3,5 219:25 220:11 221:22,23 223:6	224:8 225:11 226:12,16 correction (1) 132:20 corrections (1) 230:7 correctly (4) 66:9 104:22 112:22 225:20 correlation (2) 206:17 207:24 correspond (1) 16:6 correspondence (1) 44:3 corresponds (1) 100:23 cost (3) 39:5 182:18 224:11 costly (1) 36:15 costs (3) 29:18 135:7,8 counsel (12) 6:21 7:4 15:4,20 37:24 80:4 211:14 213:13 218:6 227:24 231:9,10 count (2) 60:2 192:16 counted (1) 59:22 country (4) 18:17 85:18 167:14 214:4 counts (1) 209:2 couple (9) 13:23 125:6,16 132:25 148:5 168:18 187:23 204:13,17 course (1) 203:25 court (16) 1:2 6:11,19 7:6 14:2 15:10,17,25 16:8 18:12 19:7 64:25 163:15 191:7 197:12 231:2 Court's (1) 13:23 courts (2) 16:24,24 cover (1) 126:18	covers (1) 108:10 create (1) 81:20 created (1) 15:3 creation (2) 81:23,25 Crebbs (1) 162:10 credibility (1) 141:19 credible (3) 125:8,12,14 criteria (1) 189:12 critical (2) 64:11 87:23 criticisms (3) 42:4,5 147:16 criticizing (2) 147:22,24 critiquing (1) 216:13 cross (1) 149:18 cross-examiner (1) 210:13 crossover (2) 97:14 98:21 crud (1) 132:15 crystal (1) 227:18 culprits (1) 137:23 culture (1) 27:12 cultured (1) 27:17 curiosity (1) 174:9 current (6) 40:10 140:19 145:3 155:4,5 218:15 currently (12) 11:8,11,17,23 12:16 12:18 153:11,16,25 173:3,4 218:14 currents (2) 206:12,18 curriculum (1) 164:7 customs (1) 145:7 cut (2)
---	--	---	---	---

119:6 189:14 cutting (1) 42:18 CV (12) 4:23 160:12 164:2,13 164:15 167:20 176:17,23,24 177:2 224:13,17	81:11 125:6 134:18 150:19,20 164:13 215:15 228:21 230:24 232:25 dated (5) 164:10 200:20 220:10 220:24 231:24 dates (9) 73:6,8 79:6 83:7 92:14,16 102:3,4 167:18 David (13) 26:11 27:5 28:8,8,14 34:22 116:6,24,24 116:25 126:20 127:8 217:21 David's (1) 117:22 day (6) 6:4 96:3 105:25 137:15 144:17 194:12 days (10) 14:18,18 17:12 18:3,6 19:10 59:23 106:2 124:20 215:5 deal (1) 132:18 dealing (4) 70:2 74:7 175:23 224:21 dealt (4) 178:7 191:24 196:16 198:14 Dear (1) 80:22 death (2) 182:4,5 debated (1) 226:10 December (16) 1:24 6:2,4,15 47:25 48:8 51:8 68:15 88:24 89:8 93:21 124:9 200:22 230:6 231:5,24 decide (5) 35:18 148:4 180:6,6 223:10 decided (2) 116:21 221:25 deciding (1) 131:22 decision (2) 130:9 131:12 decisions (1)	189:13 declined (4) 136:7,8,13 160:15 decolonize (1) 114:15 deep (4) 112:16,16 120:20 125:5 default (2) 33:19,20 defendants (5) 6:23 17:10,19 20:13 41:5 defense (1) 15:4 defenses (1) 188:10 defined (1) 194:24 definite (3) 117:8 182:6 187:7 definitely (10) 30:6 32:6 62:25 75:11 81:25 119:12 192:11 194:3 217:18 221:14 definition (1) 177:21 degree (2) 190:18 191:3 degrees (1) 167:13 deleted (1) 137:12 deliberately (1) 159:16 deliver (1) 185:16 demographic (1) 45:20 demographics (1) 110:3 demonstrate (3) 112:10 201:8,10 denied (1) 38:13 department (3) 28:3 29:21 81:11 depends (2) 39:9 224:4 DEPONENT (1) 230:3 deponents (1) 16:7 deposition (21) 1:11 6:3,9,14 14:19	15:17 16:23 40:20 49:7 77:24 95:14,20 183:7,13 196:3 197:11,11 229:22 229:25 230:5 232:4 depositions (2) 15:21 77:23 describe (8) 25:10 77:2 164:5 169:13 200:24 212:10,12,13 described (2) 42:25 185:23 describes (2) 61:10 123:23 Description (2) 4:14 232:5 design (2) 35:16 224:2 designed (1) 220:22 detail (5) 88:20 192:12 205:18 212:14 223:23 detailed (3) 109:18,20 210:23 details (2) 44:14 84:9 determine (1) 204:11 determined (1) 211:19 devastating (1) 119:13 development (1) 38:11 device (6) 39:22 181:17 202:20 204:7 206:13 211:7 devices (1) 181:18 devoted (1) 181:4 DHSs (1) 120:21 diabetes (3) 194:7,9 195:5 Diabetics (1) 194:5 diagnose (1) 52:13 diagnosed (1) 59:25 diagnosis (2) 59:18 190:19 diarrhoeal (1)	85:20 die (1) 152:22 Diego (3) 134:14,21 174:12 difference (25) 27:22 31:21 32:2,24 33:4 43:23 104:5 105:8 106:20 142:18 158:5 172:6 172:21 177:22 178:12 194:6 204:15 205:16 211:23 215:23 223:5,9,13,22 226:19 differences (3) 103:8 204:11 214:24 different (31) 13:4 14:9 15:16 18:25 25:5,15 30:19 37:6 61:3,24 62:18 68:20 87:16 91:13 99:18 103:23 141:4,5 153:17,25 154:2,17 162:9 168:21 179:9 197:10,10 203:23 204:12 224:25 227:16 differently (1) 8:9 difficile (6) 85:15,22,25 86:12,16 87:19 difficult (4) 15:8 52:12 163:21 185:7 difficulties (2) 153:20 184:12 difficulty (2) 193:20,24 direct (5) 74:25 122:15 130:5 179:23 204:5 direction (2) 86:20 137:20 director (5) 173:4,10,23 177:4,6 directors (1) 173:21 dirty (1) 187:10 disagree (1) 98:9 disclosures (1) 201:6
---	--	---	---	---

discrete (2) 99:8,10 discuss (1) 23:25 discussed (12) 152:9,18 157:11 178:6,7 179:23,23 190:14 192:11,12 192:14 217:2 discussing (4) 37:19 190:13 194:12 222:7 discussion (15) 26:14,25 33:22 40:3 43:9 123:9 130:8 134:6 138:3 142:5 204:4,8 216:3 220:19 221:18 discussions (2) 131:21 192:9 disease (3) 152:23,24 158:18 disrespect (1) 33:19 disrupted (1) 26:15 disruption (5) 25:23 32:25 33:2 191:24 207:10 disrupts (1) 158:16 DISTRICT (2) 1:2,2 disturbance (3) 23:5,23 24:21 diverted (1) 71:15 Division (1) 6:12 doctor (1) 167:21 document (42) 4:24 5:8 15:9,13,14 15:19 18:13,25 21:14,17 43:4,7,13 49:2,6 55:6 56:7,9 64:20,21 65:18 72:4 72:11 75:4,23 76:12 82:2 100:13 105:10 132:9,11 140:20 176:5,7 200:12,13 210:13 213:5 214:18 220:8,13 221:13 documentation (2) 43:19 203:10	documents (29) 4:17,18,19,22 13:22 14:9,11,14,17,17 15:23,24 16:6,16,25 17:9 18:9,21 20:13 20:17 41:13 42:20 44:2 74:20 76:11 87:3,5,14 113:19 Dog (37) 27:10,11 47:11,14,21 47:23 50:12,23 51:4 73:23 80:16 89:10 90:10,13,13 91:3,10 91:13 97:11,12 98:16 99:16 102:17 102:25 103:2,3,7 106:12 113:20 115:4 119:21,22 153:11,13,19 202:18,21 dogma (1) 184:21 doing (22) 9:2 12:6 25:15 29:19 32:20 35:23 44:25 64:3 65:8 68:22 73:5 85:25 120:9 131:8 133:19 148:12 154:16 162:2 201:17 211:17 217:25 225:2 dose (4) 83:16 84:15 85:5 185:15 dots (1) 55:20 dotted (1) 140:16 double (1) 148:7 doubly (1) 170:16 doubt (1) 20:9 downgraded (1) 30:22 Dr (23) 28:4 31:6 32:18 33:14 33:14,16,18 40:21 41:15 55:9,10 134:7 134:14 138:5 158:23 174:24 199:11 218:13,13 222:10,12 225:4 226:14	draft (13) 40:9,14 123:16,23,25 124:13,14 132:23 133:7 147:19,19,21 217:11 drafted (2) 147:15 157:12 draped (1) 26:7 draping (4) 179:4,7,8,10 draw (4) 101:8,8,11 124:21 drawing (1) 125:5 dress (4) 112:3,14,18 113:5 dressings (2) 111:15,16 DRGs (1) 61:17 drill (1) 64:10 driven (4) 35:17 85:13 86:5 184:11 driver (1) 141:12 drop (2) 38:17 136:19 due (4) 41:12,20 80:13 115:6 DVD (2) 141:13,14 Dyer (5) 2:8 7:6 63:16 80:13 154:25 dying (1) 152:25 <hr/> E <hr/> E (2) 4:2 232:3 e-mail (39) 5:2 26:13,14,22,23 42:15 44:3 122:17 122:17,21 123:18 123:19 124:7,19 129:22 130:18,23 132:22 133:3,5,5,8 133:10 134:12 144:12,13 146:11 146:17,18 147:5 148:19,22 200:18 200:20,24 201:15 201:20,25 202:8	e-mailed (1) 43:25 e-mails (8) 41:14 42:7,9,10 43:20 134:10 150:19 156:25 E14 (1) 2:17 earlier (8) 87:2,14 96:18 145:23 152:9 153:14 160:15 222:3 early (9) 69:15 113:9 114:11 118:24 126:22 127:11 144:7 168:19 189:8 ease (2) 15:16 16:9 easier (3) 100:8 108:17 129:5 East (9) 8:22,24 9:4,6,8 11:10 167:15 168:8 173:5 easy (2) 161:12 201:9 EC4V (1) 6:6 EC4Y (1) 2:12 edge (1) 205:14 Edinburgh (4) 170:12,21,24 171:18 Ediri (2) 2:18 7:5 editor (3) 147:15 157:6,9 education (5) 11:15 164:16 166:25 167:3,4 educational (1) 166:21 effect (20) 35:18,19,24 36:11 37:6 112:17 123:11 123:13 152:19 202:9,10,12,24 206:14 210:9 215:9 215:13 216:20,22 228:23 effective (4) 17:20 84:22 225:18 226:5 efficiency (1) 140:7	eight (7) 9:2 34:8 89:8,10 90:17 91:12 97:18 either (10) 14:13 17:10 19:10 20:19 103:9 111:11 114:21 118:8 149:13 158:8 elective (3) 62:14,16 63:3 electronically (3) 150:7 200:6,7 eliminated (1) 103:8 else's (1) 66:18 embark (2) 151:9,10 emissions (1) 21:21 emphasizing (1) 110:20 employee (2) 231:9,10 employment (3) 9:17 164:17 167:2 ended (2) 89:4 99:5 endurance (1) 163:7 engaging (1) 134:2 England (15) 9:6,8 18:15 39:15 46:16 116:19 117:2 136:5 170:2,2,6,24 218:7,8 231:4 English (4) 14:13 16:23 168:17 170:11 enormous (1) 62:3 enter (2) 130:17 194:13 entire (1) 212:7 entirely (2) 92:23 132:5 entitled (4) 4:24 5:8 39:19 212:19 entry (2) 117:15 185:22 enumerate (1) 16:2 epidermis (3) 59:11 60:6,7
--	---	---	---	---

episode (1) 57:3	evidence (43) 12:7,11,17,25 15:24 16:21 26:6 36:10,14 55:13 66:16 80:12 90:21 103:12 111:5 111:10,13 112:2,4 115:7 117:7 120:7 131:6 138:22 139:2 191:2,6,15,16 194:22 196:2 217:8 217:9,14,15,18,20 217:25 218:17 226:22 227:9,13,18	57:17,24 58:24 59:14 60:24 61:20 62:2,13,24 63:25 64:8,22 65:2,4,20 65:23 66:14 67:16 67:19 68:18 69:24 70:7,17,21,24 71:11 71:14,18 73:4,9 74:2,6,13,20,23 76:3 77:17,21,24 79:9,12,14,20,23 80:4,10,14,20,22 81:2,9,16 82:16,18 82:21 83:3 84:6,8 84:21 85:12,17 86:4 86:6 87:6,15 88:25 89:4 91:6,22 92:5 93:3 94:4,6,21,23 95:3,11,22 96:10,14 100:6,13,25 101:23 102:2 103:13 104:10,12 105:11 107:2,11 109:13 110:8,10 112:5,23 113:2,7,13 115:16 117:15,25 118:18 119:3,11 121:18 122:2,5,13 124:8,14 124:16 125:15 126:2,5,12,14 127:5 127:16 128:22 129:11 130:2,22,25 131:3,5,7,9 132:3,8 132:11,14 133:21 133:23 136:25 137:4,9,15 138:9 139:17 140:13,16 140:20,25 143:11 143:13 145:16,18 147:22,25 150:10 150:18 152:13,15 152:20 154:12,14 155:2,13,19 156:3,6 156:11,13,15,21,23 158:22 159:18 160:7,9,19 161:19 162:17 163:18,25 164:20 165:21 166:5,8,13 167:5,9 167:11,23 170:9,11 170:15,21 171:18 175:10 176:5,22 179:9,12 182:15 184:22,25 186:15 186:17,20 187:10 188:22 189:10,22	190:3 191:15 193:9 193:14 195:6,10,15 196:5,8,21,23,25 197:8,16 198:24 199:7 200:4,6,12 201:15 202:14 203:15,17 205:5,9 205:13 207:17 209:3 210:6 211:8 212:3,6 213:15,23 214:2 215:19 219:2 219:9,19 221:6 222:23 225:24 226:8 227:3,10 228:12 229:12,16 229:18,20	197:5,15 200:8,9 203:14,19 212:4,8 212:11 213:21,22 218:23 220:6,7 221:3
equal (2) 170:14 173:15			exhibited (1) 197:8	exhibits (8) 4:13 13:21 14:7,9,15 15:12,22 16:11
equally (3) 131:18 225:18 226:5			exit (1) 185:21	expect (3) 53:10 181:16 206:3
equivalent (5) 168:15,25 169:3 223:18 226:8			expected (1) 73:21	expecting (1) 102:12
errors (1) 149:2			examining (2) 15:23 159:22	experience (7) 32:2 77:22 86:7 147:8 169:11,15 203:25
Esq (5) 2:13,18,23 3:8,13			example (8) 40:18 110:7,16,20 178:6 185:25 190:24,25	experiment (7) 24:25 25:2,11 27:6 34:8,11 143:24
essential (1) 43:15	evolution (1) 221:15		exams (4) 168:2,3,14 171:4	experimental (3) 23:24 142:20,20
essentially (31) 9:3 12:3 24:22 27:11 28:8 33:6 35:15,23 36:3 45:3 46:9 61:17 65:13 76:19 78:15 94:17 99:13 109:6 114:15 115:17 126:3 128:14 142:15 150:3 152:22 162:4 171:7 185:10 207:20 219:4 228:3	evolve (2) 220:18 222:5		Excel (1) 57:20	experiments (5) 29:20 35:16,22 129:14,18
establish (8) 76:12 87:10 110:2,14 130:18 228:9,13 229:10	evolving (1) 117:7		Excellence (1) 11:23	expert (10) 78:18 182:8,23,25 190:16 226:22 227:5,11,12,19
established (8) 64:19 67:10 72:10 138:24 139:2,9 225:17 226:4	exact (4) 26:4 90:20 140:4 228:2		exception (1) 230:6	experts (4) 176:7 180:5 225:3 227:14
establishing (2) 17:2 66:16	exactly (6) 32:21 53:20 91:18 105:13 119:3 182:19		excess (2) 17:22 155:20	explain (4) 9:14 48:21 77:21 149:25
estimate (3) 12:13 37:13 224:12	exam (11) 7:21 168:20,22 169:9 169:19 170:3,6 171:4,4,5,6		exchange (1) 156:25	explains (1) 92:6
et (6) 25:12 34:12 126:23 128:12 169:22,22	examination (10) 4:7,8,9 7:17 24:19 160:25 168:18 204:5 227:23 229:20		exclude (1) 215:16	explanatory (1) 55:19
eundem (1) 170:2	examiner (348) 2:8 7:6,7,12,16 10:7,9 11:25 14:3,22 15:5 16:13,18 17:3,6,24 18:11,20 19:3,6,15 19:24 20:8,11,15,19 20:21,23,25 21:12 22:7,12,18,21,23 23:11 26:18 30:8 34:4,11,15 35:7 38:6,8,14,18 39:18 40:6,11,15,23 41:2 41:7,9,18,21,24 42:7,9,13 43:3,7,11 43:18 44:10 45:13 45:18 46:2,5 48:3,6 48:17,23 49:3,10,14 49:21 50:11,14 51:15 53:9,14,23 54:10,13,15 55:14 56:6,8,12 57:5,8,15		excluded (2) 60:2 164:18	explicitly (1) 72:23
evaluating (1) 154:17			exclusively (1) 70:10	exposing (1) 142:11
evaluation (2) 129:6 153:16			excuse (3) 72:5 101:11 103:2	exposure (2) 192:24,24
event (2) 18:8 176:18			executives (1) 85:23	express (1) 210:9
events (2) 26:5 95:5			exhaustive (1) 153:7	expression (2) 39:6 222:8
eventually (2) 42:19 128:12			exhibit (55) 4:17,18,19,20,21,22 4:23,24 5:2,4,5,6,8 14:15 15:9,16 18:13 19:2,3,12,14 20:7 52:19 54:18,19 81:6 81:7,14,17,18 101:4 101:5,6 122:16 129:24,25 154:23 163:24 164:3,6	exquisite (1) 80:24
everyone's (1) 100:8				extended (1)

148:10 extent (1) 16:3 extra (2) 155:3 189:19 extremely (1) 134:15 eyes (1) 59:3	151:24 162:24 163:4,12 181:4 186:25 190:20 191:8,12,22 205:12 215:25 219:12 226:9 fairly (7) 60:8 61:22 95:5 143:6 143:18 199:10 201:9 fall (6) 36:8 61:3,6,24 62:4 87:19 fallen (1) 61:2 falls (1) 36:9 familiar (15) 9:5 43:4 52:23 55:11 55:15 65:4 72:7 85:18 132:24 172:14 192:3,4 196:12 198:22 199:20 far (5) 106:21 121:14 128:3 135:2 176:4 fast (1) 98:18 FAW (1) 140:9 February (25) 50:18 84:15 88:18,24 88:25 89:6,8 93:18 93:21 96:2,4,7,10 96:24 97:9 99:4,5 102:7,20,23 105:23 105:23 106:5 110:19 114:21 February/March (1) 48:20 federal (6) 16:21 18:18 131:6 191:6 226:21 227:9 feel (3) 130:24 149:8 223:12 feels (7) 48:14 51:14 68:21 83:9 91:11 93:13 164:12 fellow (2) 171:3 174:4 fellowship (5) 168:9,11,12,17 174:21 felt (1)	85:7 femur (1) 66:5 fidelity (1) 144:22 field (6) 56:22,24 180:14 205:25 206:4,7 fifth (2) 20:17 189:25 fighting (2) 193:21,24 figure (2) 219:19 224:13 figures (1) 140:8 file (6) 19:16 20:17 48:25 49:4 52:4 197:16 files (4) 17:18 18:7 20:10,14 filters (1) 129:15 filtration (1) 129:7 final (5) 127:12 142:2 176:11 228:25 229:2 financed (2) 27:25 28:2 financial (2) 9:16 135:14 financially (1) 231:9 financing (1) 28:5 find (9) 38:15 56:15 57:8 111:11 126:24 132:12 135:2 219:2 230:7 finding (1) 47:2 findings (1) 86:23 finds (1) 15:25 fine (9) 42:17 43:18 74:13 77:18 118:9 145:17 166:13 217:5,10 finish (3) 138:7,9 169:18 finished (2) 138:10 167:19 fire (1)	82:3 first (55) 12:19 14:5 21:23 22:7 22:11,14,17 23:15 24:9,23 43:3 47:19 64:16 66:9,25 68:14 69:2,9 91:12 94:4,5 95:7 96:21 102:6 106:4 110:12 114:5 118:25 119:7 123:16,23 124:3,14 135:18,19 136:16 136:20 137:3,10 140:21 144:23 147:19 148:21 157:9 167:24 168:2 168:5 180:10,10 189:8 203:22 213:23 223:11 226:18 228:8 fit (1) 142:5 five (17) 13:2 20:10,11 93:3 98:13 99:13 102:21 102:23,24 103:4 105:5 106:8 108:10 168:7 190:6 209:21 209:22 flaws (1) 147:16 Fleet (1) 2:12 flip (2) 135:16 148:19 floor (1) 33:8 flow (15) 4:20 23:5,23 26:15 121:6 157:18,21 158:16 175:16,17 175:24 199:18 207:3 216:7,13 focus (5) 42:23 59:2,13 76:23 137:20 focused (1) 176:8 folder (1) 155:12 follow (2) 18:16 180:17 follow-up (3) 106:2 125:10 148:10 followed (1) 77:9	following (9) 5:7 26:13 104:18,18 104:21 105:4 171:22 203:11 212:20 follows (1) 7:11 fomites (1) 187:6 font (1) 200:25 footwear (1) 109:17 forced (37) 1:5 6:10 21:18 23:5 23:23 26:16 27:7,23 36:5 49:25 73:23 123:11,13 125:10 125:19 129:6 132:8 135:6 142:18 154:3 154:4 157:21 158:6 159:23 175:16,24 204:6 206:12 209:7 209:10 211:7 216:19 218:2 223:5 223:22 225:16 228:3 Forced-air (2) 4:24 199:17 foregoing (3) 230:5 231:5,6 forget (2) 82:3 144:8 Forgive (1) 194:20 forgot (1) 35:10 forgotten (1) 35:11 form (15) 34:3 52:25 65:6 119:10 162:16 187:12 205:4 206:2 209:17,24 210:5 218:16 222:21 225:5 228:11 formal (1) 68:23 formally (1) 69:16 formed (4) 68:4,7,13 175:4 forming (5) 207:16,19,25 208:17 208:20 formulate (1)
--	--	---	--	---

207:9 forth (4) 41:14 138:14 139:6 139:10 forthcoming (1) 34:19 forum (1) 32:9 forward (3) 15:8,16 219:22 forwarded (1) 201:20 found (8) 32:23 105:2 106:14 116:19 194:8 212:14 213:6,16 foundation (30) 9:13 14:10 15:13,25 16:15,17 17:2 18:10 53:8 54:5 56:3,5 62:12 64:18,20 65:7 66:3,17 71:20 72:10 73:25 76:12 77:16 77:17 81:19 100:11 103:11 105:9 130:18 139:15 four (10) 8:11 13:20 20:12,14 174:21 181:2,2,3 189:23 192:13 fourth (2) 189:24 225:14 fracture (2) 120:21 159:12 fragile (1) 157:23 FRCS (8) 168:25 169:3,6,9,15 169:19 170:2,6 FRCSs (1) 170:11 free (1) 130:24 frequency (1) 155:23 frequently (3) 182:12,13 207:15 Friday (1) 40:13 front (10) 13:19 19:13 65:18 84:4 96:9 120:13 156:21,23 195:23 205:15 frowned (1) 148:8	full (7) 7:12 65:24 96:21 110:12 122:17,17 123:3 full-time (8) 46:14,18 63:20,24 64:3 69:3,7,14 fully (1) 47:13 function (1) 226:8 functioning (1) 78:15 fund (4) 34:24 160:16 222:9 224:10 funded (3) 34:18 39:24 151:24 funder (2) 31:9 221:20 funding (12) 28:12 38:12,16,23 40:3 160:4,6,14 221:21,22 226:15 226:17 further (12) 4:9 34:6 89:17 90:3 144:23 160:18 167:14 189:21 205:20 227:2,23 231:9 future (1) 37:22 <hr/> G <hr/> Gabriel (7) 3:8 6:25 18:5 70:15 130:20 138:7 161:2 Gail (3) 65:16 67:4 74:10 gain (3) 38:16 78:24 159:10 game (3) 70:16,19 182:20 games (1) 70:20 gaps (1) 64:5 gathered (2) 51:22,24 Gauthier (4) 131:16 144:15 146:19 146:20 general (9) 10:5 58:3,18 167:25 177:24 195:16,17	227:7,8 generally (6) 8:18 61:4 173:15 177:25 180:8 220:25 generated (1) 52:11 generator (2) 11:20 145:7 generators (1) 11:19 Genevieve (2) 3:13 7:2 gent (1) 90:23 gent/teic (5) 89:20 90:12,24 91:21 91:23 gentamicin (37) 82:12 83:6,11,16,16 83:20,24 84:13,14 84:16,18,19,21 85:5 85:8 86:6,16 88:8 88:13,17 89:12,16 89:20 90:3,14,19 91:9,20 97:19 98:2 98:22 99:2 101:9,9 101:14 102:9 119:25 gentleman (1) 150:18 gentlemen (3) 169:13 179:24 212:18 genuinely (3) 86:18 117:20 176:4 geographical (2) 171:14,15 Gerlando (2) 3:17 6:17 getting (19) 27:11 42:18 66:22 71:15 79:2 94:25 99:15 100:10 124:10,10 149:17 184:3,12 194:21 198:11 205:5 219:13,14 224:18 ghost (1) 147:9 gigantic (1) 221:4 Gillson (2) 65:10,11 give (23) 85:6 101:16,17,25 106:22 133:16	138:5 142:15,16 150:11 167:13 174:16 189:16 190:15,17 191:2,15 191:16 199:23 205:6 212:13 223:11 227:12 given (17) 56:2,20 58:13 75:14 75:14 84:16 89:11 123:7,14,20 129:12 143:2 172:12 174:18,19 177:13 227:6 giving (4) 80:8 174:23 212:25 227:18 Glasgow (3) 112:8 170:24 171:18 glasses (1) 59:4 globally (2) 14:6,11 go (62) 12:3,10 14:22 15:2,11 22:13 28:6 31:4 34:5,7 38:21 41:16 42:23 45:14 49:17 51:10 52:4 59:6 63:11 68:16 69:11 77:21 80:25 82:4 84:19 87:5 88:4 92:25 99:22 100:16 109:9 118:19 122:2 122:13 124:3 131:11 144:2,2 146:10 148:24 149:17 150:7 151:8 154:22 160:19 162:21 166:11,21 167:4 174:15 175:14 176:9 183:4 189:20 200:11 201:16 205:20 211:2,2 219:22 221:3 225:7 God (1) 80:22 goes (15) 14:20 20:3 22:11 38:22 53:17 72:5 75:23 120:14 122:18 126:13 133:5 142:8 148:19 158:3 207:21 going (84)	13:11 14:6 15:7,8,16 16:9 22:3,17 24:2 34:24 37:17 39:12 42:13,16,20 43:20 64:11,18 69:19 71:20 77:13 79:25 81:18 90:4 95:14,20 99:22 100:4 101:11 116:6 117:5,5 122:8 124:13 125:21 127:10 129:5 130:16,20 131:23 135:4 137:20 140:24 141:23 143:13 146:6,24 148:19 150:11 153:23 155:24 158:13 159:8,21 160:20 162:7,20,23 165:5,5 171:18 175:20 179:22 183:7,13 190:13,15 197:11 200:2,5,14 201:18 205:20 206:22 211:13 212:17 217:21 218:22 219:22 223:25 224:11 226:22 227:3 229:23 Golden (2) 111:25 112:6 good (9) 7:18 28:21 36:14 116:7 117:7 133:14 133:19 146:14 180:6 Google (11) 165:7,8,9,12,14,17,25 166:5,10,16 178:21 Gordon (265) 2:23 4:7,10 6:23,23 7:16,17 10:11 12:9 14:25 15:20 19:9,11 19:17,20,22 20:2,6 20:20,22,24 21:2,4 21:8,11,13 22:24 23:14 27:4 30:12 34:20 35:9 38:6,7 38:10,15,24 39:15 40:2 41:9,12,20,22 42:3,8,12,17,22 43:9,12 44:10,13 45:16,19 46:3,7 48:7,12 49:16,20,23 50:15 51:11,16
--	---	---	---	--

52:21 54:10,11,14 54:17 55:16 56:12 56:14 57:11,20,25 58:7,9 59:5,16 60:10 61:8,12 62:7 62:19 63:4 64:9 65:3,6,9,21,24 66:12,20 67:20 68:19 69:6 70:10,15 70:19,22,25 71:13 71:15,20,22 72:12 73:4,7,11,20 74:15 74:24 75:4,6 76:6 76:15 77:15 78:2 79:10,16,25 80:6,9 80:13,15,21,24 81:3 81:16,17,21 82:9,23 83:4 84:11,12,24 86:14 87:9,11,12,25 89:2,5 91:7 92:2,7 93:5 94:5,12 95:12 95:23 96:13,15,16 99:19 100:10,18,25 101:3,7,21,25 102:3 102:5 103:16 104:11,13,14 105:14,20,21 107:3 107:6,15 108:8,21 109:16 110:9,11 112:7 113:10,17 115:22 117:4,17 118:10,21 119:5,17 121:23 122:14 124:17 126:10,13 126:15,17 127:6,7 127:17 129:17,25 130:3,4,12,20,22 131:10 132:12,15 132:17 134:4 137:11,14,17 138:2 138:7,12,25 139:4 139:22 140:13,19 140:21 141:10 143:20 145:19,20 146:9 148:3 150:16 150:22 152:14 153:10 154:21 155:3,9,15,25 156:5 156:8,12,16,18,22 156:24 158:24 159:20 160:13,18 162:16 163:18 205:4 206:2 209:17 209:24 210:5 218:16 222:21 225:5 227:20,22,23	228:15 229:17 Gordon's (1) 174:10 governance (3) 53:12 172:9,12 government (2) 67:12 85:21 gowning (2) 179:8,11 grade (4) 149:5 150:4,5 153:3 grades (1) 149:23 grading (2) 150:3,3 Grail (2) 160:3,4 grant (1) 158:12 granted (1) 24:4 graph (5) 120:13 133:16 197:19 211:2,4 grateful (1) 125:3 gray (1) 29:7 great (1) 157:5 greater (4) 17:19 191:8 210:3 219:15 ground (1) 162:22 group (24) 15:22 16:11 34:5 43:24 61:25 67:3 68:3,14 69:9 90:23 91:20 96:23 108:18 108:18,18,19,22,23 115:7 120:22 125:11 159:16 175:23 211:21 groups (6) 61:24 62:4 76:20 108:16 110:4 153:4 grow (2) 28:19 188:7 growing (1) 188:5 grows (1) 17:24 guess (7) 81:5 101:3 155:16 163:10 187:13	190:20 201:24 guessing (1) 39:15 guidance (6) 12:4,15,23 13:2 217:11 222:13 guidelines (3) 11:19,19 218:15 guy (2) 71:5 78:18 guys (2) 33:18 146:23 <hr/> H <hr/> HAI (2) 72:19 73:13 half (6) 6:16 37:7 57:21 122:20 155:17,19 Hamer (1) 192:7 hand (8) 19:22 72:20 79:8,13 101:19 110:12 112:23 144:23 handle (1) 46:19 hands (1) 114:17 hang (3) 17:6 195:10,10 happen (2) 35:16 187:15 happened (8) 44:22 74:8 86:3 87:22 92:19 147:13 148:15 149:12 happening (3) 120:15 147:14 219:4 happens (3) 12:23 36:6 80:18 happy (5) 37:25 98:7 124:25 144:21 155:14 hard (2) 7:22 121:8 Harper (2) 222:10,12 hassle (1) 29:18 head (7) 11:8,11 111:7 132:16 163:16 173:5,18 headquartered (1) 6:18 health (4)	11:22 67:2,7 172:11 Healthcare (9) 2:23 7:15 9:13 66:3 66:22 221:21,23,25 224:16 healthy (2) 150:4,5 hear (2) 20:16 79:12 heard (10) 22:12 26:11,19 122:5 155:22 163:9 185:17,23 196:5 216:15 hearing (1) 195:23 hears (1) 31:17 hearsay (6) 35:6 66:11,17,19 69:5 137:25 heart (3) 115:21 149:13 152:23 heat (1) 157:23 held (2) 6:14 175:12 HELEN (2) 231:4,23 help (3) 111:13 146:13,15 helped (1) 135:7 helpful (1) 57:13 helps (2) 9:7 167:20 hematomas (1) 94:25 hemiarthroplasties ... 120:21 hemiarthroplasty (1) 159:13 heparin (6) 92:23 211:19 212:22 214:20,25 215:8 Hexham (3) 10:5,15 54:24 Hey (1) 202:2 hide (1) 134:6 hides (1) 137:24 hiding (2) 133:14,19	hierarchy (2) 36:7 173:11 high (10) 6:11 13:23 16:8 66:7 69:13 85:5 120:14 159:13,16 167:7 higher (5) 61:4 159:15 193:2 198:19 223:22 highlight (1) 150:25 highlighting (1) 151:4 highly (2) 176:6 184:5 hindsight (1) 18:5 hint (1) 144:9 hip (32) 30:14,15,25 31:3,4,13 33:24 45:22 57:5 58:21 60:22,25 61:2 62:9 82:11 85:3 104:21 105:4 113:24 115:12 120:21 136:3 159:12,14 165:16 174:5 178:4 193:10 196:17,19 198:15 212:25 hips (3) 190:3 198:6 202:10 hire (1) 162:8 history (1) 70:14 hit (1) 180:10 HIV (1) 152:24 hoc (1) 29:20 HODGES (1) 3:6 hold (6) 38:4,5 142:9 143:15 171:7 195:22 holding (1) 71:7 Holl-Allen (43) 2:13 7:4,4 17:4,8 19:19 20:3,5,9,12 20:16 21:6 23:10,12 40:12,17,24 41:5,8 48:11,24 49:13 51:9
--	--	--	---	--

60:7 84:7,9 87:14 87:15,17 92:3 100:20,22 122:4 128:21,24 129:4 139:4,19 155:12 194:20 195:12,21 213:14 Holy (2) 160:3,4 home (1) 179:25 honest (3) 132:6 141:9 223:18 honestly (2) 141:21 206:25 honesty (3) 26:22 53:24 146:11 hope (1) 190:3 hopefully (4) 30:10 120:23 158:13 189:17 hoping (1) 143:13 hose (1) 21:22 hospital (29) 9:11,18,22 10:4,5,6 10:20 28:23 29:3,14 45:23 51:18,20,21 52:11 57:3 58:12 61:16 83:11 86:2 105:24 110:7 111:24,25 112:8 117:25 172:17 180:21 181:18 hospital's (1) 82:10 hospitals (12) 9:15,19,20,20,21,23 10:20 45:23 54:23 55:2 152:18 214:4 host (6) 185:22 188:9 193:18 194:13 210:4,18 hosts (1) 193:20 Hot (37) 27:10,11 47:11,14,21 47:23 50:12,23 51:4 73:23 80:16 89:10 90:10,13,13 91:3,10 91:13 97:11,12 98:16 99:16 102:17 102:25 103:2,3,7 106:12 113:20	115:4 119:21,22 153:11,13,19 202:18,21 hour (3) 80:23 193:12,12 hours (3) 155:7,17,19 Houston (1) 3:7 HPA (4) 66:7,23,25 67:2 huge (3) 100:10 174:17 182:2 Hugger (61) 1:5 6:10 47:6,10,19 48:19 50:12,16,23 51:12 63:18 79:3 80:16 83:21 88:11 88:15,21 90:17,18 90:22,25 91:2,8,15 91:16,19,24 93:25 97:8,13,18 98:13,14 99:3,11,14,14,20 102:14,15 103:5 105:6 106:9,16 108:11 114:19,23 115:2,3 119:22 154:6,7,11,15,20 161:4 186:13 206:13 207:11 208:24 219:16 huh (1) 19:9 hundred (1) 150:8 hundreds (2) 161:3 186:17 HX (1) 54:24 hyperthyroidism (2) 150:23 151:16 hypo (2) 150:23 151:16 hypothermia (4) 12:5,15 225:19 226:6 hypothesis (4) 223:4,8,14,15 hypothetical (1) 37:22 <hr/> I <hr/> idea (4) 20:25 127:21,24 189:15 Ideally (1) 140:2	identification (14) 19:14 20:7 52:19 57:8 81:7 101:6 122:16 164:3 197:15 200:9 203:19 212:8 213:22 220:7 identified (4) 10:3 16:4 57:18 60:19 identifier (1) 57:23 identifies (2) 127:19 195:13 identify (11) 15:9 16:3,25 18:9 23:2,21 43:5 44:11 58:17 71:2 76:11 identifying (4) 15:21 16:12 18:12 76:20 ignore (1) 48:22 ill (1) 11:13 illegal (1) 85:10 imagine (5) 53:10 73:17 74:10 81:12 223:21 immediately (1) 10:18 impact (8) 32:25 33:3 37:16 115:25 116:2,3,5 179:20 impartial (2) 133:15 137:23 implant (15) 178:4 183:19,25 184:4,5,17 189:11 189:21,24,25 194:17 206:23 207:12 219:24 220:5 implemented (2) 115:23 119:18 imply (2) 123:10 141:17 important (5) 49:14 104:7 179:25 180:10 184:3 impossible (1) 49:11 impression (1) 75:22 impressive (2) 148:25 204:3	improper (2) 15:11 39:16 improved (1) 140:7 inadmissible (1) 191:7 inadvertent (2) 225:18 226:5 include (2) 124:25 195:25 included (8) 59:20 60:2,5 74:2 97:18,21 100:14 164:15 inclusive (1) 165:14 increase (15) 86:10,11,17,19 87:21 92:17 192:15 206:7 208:21,22 209:14 209:21 210:2,15 214:9 increased (7) 27:13 88:3 90:3 104:17 211:6 214:9 228:4 increases (4) 193:14 209:2 210:16 216:14 independent (2) 68:10 172:10 index (4) 4:13 164:25 200:12 200:16 indicate (3) 58:2 60:18 210:15 indicated (3) 59:12 60:18 116:18 indicates (2) 135:24 217:15 indicating (2) 101:8 218:7 indication (3) 17:17 56:16 61:22 indicator (1) 180:11 individual (3) 153:8 173:15 194:22 individuals (1) 173:10 infected (1) 188:20 infection (172) 12:7,8 13:13 37:5,7 37:10 39:10,23 43:24 44:16 45:5,8	46:18,19 49:24 52:12,16 56:2,16,21 57:9 59:11,21 60:9 63:11,13 65:17 67:5 67:10,12,14 68:2,5 69:13,17 70:3,11 71:4,8,16 74:18 76:19 78:22,25 80:19 85:15,20 86:10,17,20 87:24 88:2,3,6,7 97:17 103:24 104:2,3,6,17 104:19 105:2 106:14,16,20,23 108:9 110:5,6,18 111:9,14 112:14 115:7,21,25 116:2,4 116:5,20 118:7,8 119:13,19 120:3,7,8 120:18 123:5,7,14 123:19 125:2,5 133:16 142:7 143:21 144:6 149:14 157:20 158:7 159:13,15,16 159:25 160:10 168:11 175:9,13,13 177:22,23,24 178:2 178:3,13 183:17,21 183:23 184:3,6,10 184:12 185:10,17 185:19 186:15 187:8,14,22 188:12 189:4,6 190:7 193:2 193:8,18 194:9,13 195:18,19 198:19 202:16 204:20 207:21 208:8 210:17,21 211:19 211:22,23 214:15 214:21 215:2,10,13 215:17,23 217:20 217:22 218:3 219:15,25 220:5 221:23 222:14 223:12,22 224:15 224:16 228:4 infections (40) 12:12 37:16 39:8 45:21 52:25 73:14 73:22 76:21 80:17 84:23 118:23 119:8 125:6,16,19,25 126:7 177:18 178:10,23 179:2,5 181:9 182:9,17,24
---	---	--	--	---

184:16 185:8 188:5 190:25 193:21 195:16,17 216:7,14 217:17 226:24,25 227:8,8 infectious (3) 158:18 185:20,25 influence (8) 39:22 49:8 76:25 111:10 195:16,18 195:19 226:15 influenced (1) 103:9 information (6) 45:20 67:6 101:18 159:10 166:8 205:15 informing (1) 66:7 initial (2) 39:11 124:14 initially (6) 25:14,15,17 51:22 62:8 148:6 injections (1) 94:9 injured (1) 153:23 INN (1) 2:11 input (1) 129:13 inquiry (2) 17:15 201:2 insignificant (1) 87:19 insofar (1) 149:20 instance (5) 22:14 33:9 153:2 165:15 178:5 Institute (1) 11:22 instituted (3) 110:7 115:11 118:22 instrument (2) 187:10,13 instruments (3) 187:14 206:24 207:12 insult (1) 7:23 intake (1) 129:6 intention (1) 115:10 interest (5)	39:2,6 71:17 159:7 222:8 interested (3) 26:3 33:24 231:10 interesting (5) 147:3,4 203:13,21,24 interests (2) 17:14 100:3 internal (3) 155:14 156:3,6 international (2) 174:7 182:11 internationally (2) 95:10 175:5 internet (1) 166:10 interrupt (3) 39:16 48:24 167:17 interrupting (2) 130:21 194:20 intertwines (1) 43:10 intervene (2) 40:17 139:4 intervention (2) 37:7 159:21 interventions (3) 123:12 155:21,22 interview (2) 75:18,20 interviewed (2) 72:21 75:16 introduce (1) 6:21 introduced (4) 113:15 115:9 120:5 142:12 introducing (1) 205:9 introduction (1) 104:19 invented (1) 111:25 investigator (2) 158:11,15 invited (1) 182:10 involve (3) 29:16,18 187:11 involved (16) 27:11 29:22 30:3,6 37:14 81:23,25 204:22 220:21 221:14,16 222:2 224:2,19 226:15 231:9	involvement (7) 38:11 127:8 128:10 128:13 223:25 224:23,25 involving (1) 198:5 Ireland (1) 170:23 isolated (1) 116:5 issue (12) 32:25 37:15 39:3 41:13 67:9 95:9 115:24 139:16 143:21 201:8 211:13,15 issues (2) 53:12 194:23 items (2) 39:21 76:17 iterations (1) 220:16 <hr/> J <hr/> January (5) 88:25 89:6,8 93:21 114:22 JNE/FLN (2) 1:7 6:13 job (10) 1:25 6:12 45:5 51:25 57:2 133:14,19 150:10,11 177:6 jobs (1) 11:14 join (1) 170:14 joined (2) 168:4 171:5 joint (54) 9:3 37:11,16 46:10 49:24 54:24 60:9 61:6 62:18 119:8 120:8,18 121:19 126:4,6 168:10 175:9,14 177:18,23 178:3,23 179:2,5 180:19,25 181:6,9 181:10 182:9,24 183:17,20 184:6,16 185:8,12 187:22 188:12,21 189:3 210:17 213:8,10 214:15 216:7,14 217:17 218:2 219:15 226:24,25	227:7,8 Jonathan (2) 2:13 7:4 Jonathan's (1) 87:2 journal (17) 22:18,19 32:10 72:6 75:17 76:3 116:19 117:2 145:8 165:24 180:3,19,25 213:7,9 218:7,8 journals (6) 166:11 180:18,20,23 181:2,3 JTO (1) 76:3 Jubilee (7) 111:22,23,23,25 112:3,6,18 judge (3) 169:14 182:25 227:17 Julie (3) 65:10,11,15 July (23) 45:24 46:11 47:5 48:19 50:16,17,18 51:7 63:19 72:6 84:15 88:22,23 89:7 97:8 98:17 99:3,21 102:20 106:6 220:24 221:17 222:7 jump (1) 107:17 jumped (1) 106:16 jumping (1) 107:23 June (12) 10:13 47:25 48:8,9 50:4,12 51:7 102:23 117:25 121:13 201:16,18 junior (5) 8:10,20,22 22:10 169:6 jury (4) 31:16 169:14 179:24 212:18 Justice (1) 6:12 justify (1) 95:4 <hr/> K <hr/> Kay (4)	1:24 6:19 231:4,23 keen (4) 22:14 29:17,19 151:9 keep (4) 64:22 71:15 164:21 197:4 keeping (3) 217:2,15,19 KENNEDY (1) 3:6 kilogram (5) 84:16,19 85:6 90:8 102:10 Kimberger (2) 126:19,25 kind (6) 37:21 42:18 43:10 82:4 121:8 148:7 kinds (1) 37:2 Kingdom (4) 1:16 2:12,17 6:6 knee (15) 23:6 45:22 57:5 62:10 82:11 85:3 104:21 105:4 113:24 115:12 119:8 196:17,19 198:15 212:25 knees (1) 202:9 knew (2) 191:18 201:17 know (131) 15:3 25:5,18 28:9 29:18 31:11,12 32:12 33:5,6,10 36:13 42:12 44:8 53:12,24,25 54:3,4 54:11,21 55:18 59:18 63:6,10,12 65:2,10 68:21 71:7 75:15 76:13 78:23 82:14 86:18,18 87:4 87:8 98:25 100:4 107:13,14 111:8 113:14,16 119:15 120:4 123:24 124:5 126:21 127:9,13,14 127:23 128:13 129:9 132:11 133:4 134:17 136:20,24 137:11 139:8 140:4 141:2 143:4,25 145:14 146:12,15 146:16,16 148:14
---	---	--	--	---

149:15,16,23 152:3 152:4 153:6 154:12 154:19 157:9 162:24 163:7,11,11 163:21 171:19 174:24 175:2,8 176:4,23 182:10 183:2 184:19,20 188:25,25 191:11 192:5,7 193:3 198:11 199:11,14 199:14,15,19 200:15 202:2 204:3 204:13 205:9 207:3 207:4 210:6,19 213:17 215:3 220:15,16,17 221:25 222:10,12 222:17,19,20 227:10 228:23	30:24 Lancet (2) 116:25 117:19 large (8) 36:13 55:25 116:7 120:22 177:19 180:20 181:6,8 largely (2) 123:13 181:8 larger (1) 79:19 largest (1) 208:8 late (3) 27:6 118:15 119:9 latest (1) 44:8 law (4) 14:13 19:9 46:16 171:2 lay (2) 42:14 43:15 lays (1) 15:13 lead (9) 107:13 130:14 131:14 131:16,17 132:3 144:21 145:2,9 leading (8) 58:5,11 82:8 99:17 108:5,14 116:23 158:11 leads (2) 65:16 67:4 leak (1) 95:2 Leaper (15) 26:11 27:5 28:8,8,12 28:14 29:23 33:14 33:14,15 34:22 116:6,24 126:20 127:19 Leaper's (4) 116:24,25 127:8 217:21 learn (1) 78:17 learned (1) 30:18 leave (6) 8:17 43:13 109:14 133:8 134:10 151:2 leaves (2) 130:9 131:12 lecture (2) 148:12 201:17	lectures (1) 177:13 led (3) 17:23 159:4 211:20 left (6) 8:15 93:3 101:18 110:12 112:23 227:21 legal (1) 6:17 Legg (2) 192:3,5 legs (1) 12:3 length (3) 57:21 152:9 193:8 let's (28) 9:25 12:10 18:8 31:16 35:13 42:7,9,23 43:3 49:17 55:6 58:10 70:15,17,21 71:14 74:20 75:23 76:23 93:6 95:12 96:15 104:7 160:19 167:3 212:4 213:21 220:6 letter (6) 147:15,19,21,23 157:9,11 letters (6) 54:21,21 66:7,22 67:16,22 level (5) 36:10,14 167:5,5,7 Lever (1) 17:18 Liability (2) 1:6 6:11 liberty (1) 79:18 licensed (2) 225:17 226:4 life (2) 100:8 182:7 light (2) 48:18 59:2 likelihood (2) 152:21 210:17 likes (1) 129:15 Likewise (2) 149:5,23 limb (1) 212:23 limit (5) 14:11 62:9 171:9,15	191:6 limited (2) 2:16 69:22 line (14) 69:19 101:8,8 115:9 117:9 120:11 130:8 131:11 140:16 142:8 157:3,24 225:14 226:2 lines (1) 48:17 link (6) 106:23 165:5 193:7 194:9,10 223:2 linked (4) 146:12 151:19 193:4 219:6 lion's (1) 24:19 list (2) 37:18 150:24 listed (5) 17:12 21:23 111:3 176:22 230:6 listens (1) 30:11 Litchy (1) 126:19 literally (1) 189:14 literature (7) 104:20 105:3 120:11 178:20 208:6,13,19 litigation (9) 1:6 6:11 161:4,9,15 161:18,24 162:14 162:15 little (11) 42:20 43:10 52:3 58:13 90:3 118:18 121:5 165:21 211:2 222:3 224:4 live (3) 40:10 44:19 82:2 LiveNote (1) 231:4 LLP (1) 6:5 load (2) 27:13 114:16 loads (3) 67:24 136:16,16 locally (1) 67:4 lodging (1) 135:7	logbook (1) 169:21 London (7) 1:16 2:12,17 6:6,15 16:8 231:4 long (12) 8:7 10:22 28:20 59:21 68:24 149:10 169:7 172:22 187:25 188:6,10,19 longer (6) 42:21 125:10 148:14 155:22 192:23 193:2 longest (1) 188:22 look (46) 12:17 33:3,25 36:16 37:15 42:7 44:19 45:5,9 52:17,23 55:11 57:12,22,24 64:11 65:18 82:22 86:22 96:15,21 104:7,15 118:18 123:3 132:20 133:9 133:15 135:17 137:23 140:16 144:25 151:8 165:22 195:3 197:19 201:15,18 202:8 203:11 205:18 213:11 214:18 215:5 225:14 229:7 looked (12) 24:20 44:22 51:4,17 56:15 64:5 112:11 124:21 147:5 166:19 211:17 216:19 looking (22) 25:10 39:8 55:21 56:17 71:18 78:23 83:22 102:2 103:24 103:24 104:10 107:6 108:19 120:12 137:18,21 210:13 212:11,16 214:23,24 215:15 looks (18) 21:18 23:4,22 50:10 53:21,24 55:4,15 59:13 102:8,11 103:21 124:20 152:22 168:17 204:3 205:16 215:4
---	--	---	--	---

lost (1) 165:21 lot (19) 8:14 31:14 99:2 111:12 112:21 118:6 128:19 129:7 129:8,13,15 149:5 149:19 159:6 178:7 178:7 183:2,2 212:14 lots (14) 12:25 36:20,21 37:4,6 67:23 73:18 109:18 119:16 123:11 126:6 136:14 208:2 220:25 love (2) 100:4 125:22 low (10) 67:11,14,14 202:15 211:18 212:21 213:2 214:19,25 215:7 Lowdon (3) 65:16 67:4 74:10 lower (3) 19:22 83:16 212:22 lowered (1) 90:2 lucky (1) 142:11 lumped (1) 133:4 lung (1) 152:23 lungs (1) 12:3 <hr/> M <hr/> M (4) 136:20 139:12,18,20 M1 (2) 137:9,11 M2 (1) 137:4 M3 (3) 136:20 137:18 138:11 M4 (1) 137:13 M7 (1) 141:16 M9 (3) 140:3,17,18 machine (1) 231:6 machines (1)	21:19 main (8) 44:4,5,6 85:4 142:5 142:25 148:8 185:4 maintain (1) 77:5 major (2) 118:3 164:18 make-up (1) 173:16 making (5) 109:9 125:12 133:15 149:3 155:10 management (3) 9:16 40:22 76:17 Manchester (1) 182:13 manner (1) 16:10 manufacturer (1) 181:17 manuscript (1) 124:11 map (3) 98:8 99:23,24 mapped (1) 98:5 March (17) 48:20 50:3,6,11 84:2 84:17 88:24 89:4 91:8 97:10 98:16 99:21 102:8,22,23 200:20 201:24 marginal (1) 78:24 mark (40) 14:15 43:25 48:16 53:5 81:5,14,17 101:2,3 122:21 123:17 124:2,6,24 126:19,19 127:20 131:21 133:10,18 134:12 136:22 140:8 144:14 146:19,22 148:22 148:25 150:23 157:12 163:24 197:5,11 200:8 201:8 203:14 212:4 213:21 222:10,12 marked (16) 19:14 20:7 52:19 81:7 95:5 100:24 101:6 122:16 164:3,5 197:15 200:9 203:19 212:8	213:22 220:7 marker (2) 43:15 195:20 markets (1) 181:17 marking (2) 16:11 197:16 markings (3) 48:15 49:8,12 massive (2) 150:10,11 Master (7) 17:16 40:10,13,14 69:23 195:24,24 material (4) 13:20 17:17,21 228:23 materials (1) 16:10 matron (2) 65:12,15 matrons (1) 65:11 matter (11) 6:10 18:4 38:17 39:14 69:20 90:4 131:3,4 195:11 196:2 227:16 matters (5) 82:25 191:17 195:22 195:25 205:14 MBBS (1) 167:14 McGovern (75) 24:9,18 25:14 30:3 31:6 32:18 33:14 34:12 42:23 46:25 59:19 62:9,20 70:5 70:8,10 73:3 82:17 83:10 84:6 87:8 88:19,21,22 92:16 100:23 101:16 108:7 109:21,24 110:25 122:21,24 123:21 126:25 133:11 134:7,9 135:11,25 138:5 144:14 146:3,20 147:17 148:23 157:2 178:6 191:24 196:16,19,24,25 197:6,9,13 198:4 202:3,23 204:20 205:3,7 206:10,11 207:14 208:25 211:13 215:8,16,20	216:13 218:22 219:12 224:8 227:24 MDL (1) 1:7 MDU (1) 2:16 mean (75) 9:4 18:2 22:7 31:12 31:17,19,24 33:10 34:16 36:20 44:18 52:6 53:16 60:20 61:23 62:3,25 63:9 67:12,23 69:10,25 73:17 78:21 81:10 88:2,23 90:20 91:15 91:16 94:7 95:6 96:5 109:22 113:14 113:21 115:16 119:12 120:16 124:12 125:9,14,18 128:10 132:25 133:24 134:21 136:14 138:16 141:5,21 142:14 147:12,18 151:23 157:13 167:17 170:19 171:10 177:24 178:14 182:5 187:12 194:3 202:12 209:13 211:8 218:18,24 220:25 221:14 224:6 227:10 228:17 229:9 means (8) 22:9 113:3 123:24 125:19 126:3,4 158:11 159:9 meant (3) 63:2 171:14 202:15 measure (4) 36:6 61:5 180:11 211:21 measures (3) 110:6 112:11 152:22 measuring (1) 35:24 mechanism (1) 9:17 mechanisms (1) 184:9 medical (8) 8:15,17,18 31:18 181:17 190:18,19 191:4	medication (1) 185:9 medicine (4) 117:3 167:13 218:7,8 meet (5) 107:19,20 116:6 187:17 217:21 meeting (17) 30:10 31:2,5 68:14,23 69:2 136:5,7,9,15 165:16 174:15 175:12,15,19,20 222:14 meetings (7) 12:17,25 26:10 32:11 162:12 166:2 182:12 Melling (2) 116:10 117:23 melt (2) 153:21,21 member (4) 67:5 174:2,5,7 memory (4) 86:10 92:24 121:14 174:8 mention (4) 140:7 142:7 228:19 229:4 mentioned (6) 119:25 146:22 169:25 174:9 181:25 201:16 MESHBESHER (1) 3:12 message (4) 22:16 125:6,8,16 met (10) 28:7,10 69:9 161:5,7 161:11,13,17 192:6 222:15 meter (1) 207:7 methicillin (2) 113:24 114:9 method (2) 225:15,23 methodology (1) 69:18 methods (9) 31:21 178:22,25 179:4,6,7,8,8 181:13 Michael (249) 1:1,12 2:1 3:1 4:1,6 4:23 5:1 6:1,3,10
--	---	--	--	--

7:1,9,14 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 21:1 22:1 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 36:1 37:1 38:1 39:1 40:1 41:1 42:1 43:1 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1 52:1 53:1 54:1 55:1 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1 71:1 72:1 73:1 74:1 75:1 76:1 77:1 78:1 79:1 80:1 81:1 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1,14,20 96:1 97:1 98:1 99:1 100:1 101:1 102:1 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1 116:1 117:1 118:1 119:1 120:1 121:1 122:1 123:1 124:1 125:1 126:1 127:1 128:1 129:1 130:1 131:1 132:1 133:1 134:1 135:1 136:1 137:1 138:1 139:1 140:1 141:1 142:1 143:1 144:1 145:1 146:1 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1 162:1 163:1 164:1 165:1 166:1 167:1 168:1 169:1 170:1 171:1 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1 180:1 181:1 182:1 183:1,7 183:13 184:1 185:1 186:1 187:1 188:1 189:1 190:1 191:1 192:1 193:1 194:1	195:1 196:1 197:1 198:1 199:1 200:1 201:1 202:1 203:1 204:1 205:1 206:1 207:1 208:1 209:1 210:1 211:1 212:1 213:1 214:1 215:1 216:1 217:1 218:1 219:1 220:1 221:1 222:1 223:1 224:1 225:1 226:1 227:1 228:1 229:1,23 230:1,5,23 231:1,5 232:1,4,24 microbiological (1) 28:13 microbiologist (4) 27:14,15 28:16 29:23 microbiologists (2) 33:22 34:6 microbiology (4) 29:14,20 33:13 136:12 middle (10) 23:3 25:3 34:13 39:16 99:13 102:6,25 108:10 130:21 133:9 Mike (13) 7:14 17:9 55:17 75:7 126:18 130:14 131:14 133:11 135:25 137:6 140:4 146:19,22 milligrams (7) 84:16,18,18 85:6 90:8 102:9,10 million (1) 36:17 millions (1) 183:24 mind (2) 103:23 177:22 mine (6) 19:24 20:15,15 58:24 211:20 221:3 ministerial (1) 52:3 Minneapolis (6) 2:22 3:13 135:11 201:3,11,13 Minnesota (6) 1:2 2:22 3:13 129:18 129:19 145:23 minor (1) 27:15	minute (2) 140:25 212:13 minutes (5) 30:21 73:5 93:3 155:7 157:12 miscellaneous (1) 14:14 missed (1) 79:9 missing (1) 40:6 misstates (5) 45:12 62:11,23 103:11 105:9 misunderstood (2) 217:6,7 mix (1) 86:6 Mm-hm (3) 83:18 90:16 135:21 mobilized (1) 33:8 mocked-up (1) 25:2 modalities (1) 74:17 modality (2) 37:16 228:5 mode (2) 185:21 186:22 models (1) 139:25 molecular (6) 211:18 212:22 213:2 214:20,25 215:8 moment (4) 42:10 70:7 139:5 163:20 money (2) 28:9 171:7 monitoring (1) 225:15 month (11) 93:11 96:11 102:25 103:2 104:24,25 105:4,8 106:13 108:10 222:15 months (52) 9:2 10:14 34:8 48:13 48:14 50:9,22 51:3 51:6,12,15 89:9,10 90:10,17,17,25 91:12,18 93:16,21 93:24 94:2,15 95:3 95:25 96:25 97:10 97:13,18,21 98:13	98:16 99:13 102:21 102:23 103:4,7,21 103:22 105:6 106:4 106:8,15 153:18 154:8,11 162:4 188:13 189:8 220:18 222:6 Montrose (1) 3:7 mortality (2) 153:3 182:6 move (4) 66:11 85:9 107:12 124:18 moved (2) 46:18 64:3 movements (1) 157:22 moving (5) 25:4 33:6 40:24 49:19 66:14 MR5 (1) 137:13 MRR (1) 139:17 MRR1 (3) 135:20,22 137:2 MRR10 (3) 140:6,17,22 MRR20 (2) 142:3,8 MRR6 (1) 141:11 MRR8 (3) 139:24 140:17,23 MRSA (3) 85:22 113:25 115:3 MSSA (4) 114:20 115:5 120:4 190:25 multi-centre (1) 212:21 multi-disciplinary (2) 68:13 69:8 multiple (6) 14:8,9 36:11 57:22 68:13 181:23 <hr/> N <hr/> N (1) 4:2 Nach001 (1) 133:12 Nachtsheim (6) 123:22 144:15 146:4 146:20 148:23	213:5 name (10) 6:17 71:6 128:8 161:2 166:11 187:6 199:22 225:11 230:23 232:24 named (3) 22:8 69:12 213:23 names (1) 7:12 national (5) 11:22 64:2 67:3 174:2 177:5 nationally (1) 67:7 natural (2) 145:9 159:5 nature (1) 37:3 necessarily (6) 32:12 61:18 85:18 166:3 195:7,10 neck (1) 66:5 need (32) 36:20,24,25 37:3,5,8 52:14 59:3 64:24 74:14 91:17 92:11 120:17 125:4 138:4 140:7 141:12 144:2 152:6 154:22 157:8 157:25 159:17 169:21 183:4,16,19 183:23 185:14 194:12 199:2 213:4 needed (3) 79:4 158:4 164:23 needs (2) 19:15 216:18 negative (5) 31:14,19 33:23 35:4 136:11 Neils (1) 148:24 net (1) 165:25 network (2) 180:21,21 never (9) 62:12 100:15 128:3 141:20 147:11 148:13,18 161:5 166:19 nevertheless (3) 44:7 125:23 215:19 new (16)
--	--	---	--	---

6:19 8:25 9:2 10:5 10:12 18:17 116:19 117:2 125:4 168:9 168:12,13 171:17 189:6 218:7,8 Newcastle (1) 167:12 NHS (7) 9:13 11:17 46:16 66:3 85:13,14,16 nice (9) 11:18,21 12:4,7 13:11 13:17 134:14 217:11 222:13 nodding (1) 163:16 Nods (8) 50:24 75:9 92:10 96:20 97:2 118:13 187:3 192:20 non-trauma (4) 61:10,21 62:9,22 normally (7) 62:14 142:12 180:4,6 182:3 220:19 222:5 normothermia (1) 77:6 North (12) 8:22,24 9:4,6 10:19 10:21 11:10 54:25 167:15 168:8 173:5 222:14 Northumberland (1) 7:15 Northumbria (18) 7:14 9:9,11,13 10:4 10:12,17,22,25 11:3 11:12 29:13 66:3,22 67:21 72:24 142:7 154:10 nose (1) 114:17 noted (1) 70:15 notes (5) 26:20 142:5 150:8,9 151:13 notice (1) 155:20 noticed (1) 78:19 notified (1) 31:9 November (5) 51:7 88:23 89:7 93:20 164:10	NT (1) 54:24 null (1) 223:4 number (33) 4:14 6:12 15:10 18:7 19:4,25 37:13 58:8 76:11,13 78:22 95:13,19 141:5 156:13 163:24 164:6 177:19 180:20 182:2 183:6 183:12 196:22 197:5,7 200:3,8 203:14 212:5 218:23 219:3 220:6 221:3 numbered (4) 5:2,5 230:5 231:5 numbers (13) 19:2,3 21:5 39:4 55:6 125:7,17 126:2 141:4 159:17 204:10 213:19 223:10 numerous (2) 162:23 209:11 nurse (5) 65:13,15 71:3 186:11 207:6 nurses (5) 51:24,25 65:14 69:3,8 nursing (4) 22:19,21 45:3 73:17 O obese (3) 76:21 193:14,23 obesity (5) 151:2,5,19 193:4 195:5 object (17) 14:16 15:7 37:17 64:18 69:19 77:13 81:18 100:13 162:16 205:4 206:2 209:17,24 210:5 218:16 222:21 225:5 objected (1) 195:23 objection (65) 13:25 14:3,5,6 15:5 16:15 19:7 34:3 35:5 37:17 38:8,20 39:11 45:12 53:8,19	54:5,10 55:12,12,13 56:3,4,8 58:5 62:11 62:23 64:22 65:6 66:11,19 69:5 70:15 72:10 73:2,15,24 74:19 77:18 86:25 87:2 99:17 100:5,12 100:15,19 103:11 105:9 108:5,14 116:23 119:10 130:11,16 131:7 133:20 136:23 137:25 138:6,21 145:12 163:19 213:12 228:11 229:11 objections (7) 41:3 56:11 64:23,24 71:20 100:10 155:10 observation (1) 44:16 observational (1) 110:5 obtain (1) 202:24 obtained (1) 202:3 obviously (9) 75:12 82:13 90:6 111:3 137:5 147:12 147:13 151:19 180:10 occur (2) 184:16 185:20 occurred (14) 37:7 83:21,25 88:10 88:12,13,14,16 91:23 93:24 98:2 99:10 109:17 111:2 October (11) 49:7 51:7 53:14 59:14 59:15,25 63:17 88:23 89:7 93:20 112:22 odds (5) 218:23,24,24 227:25 229:3 offer (2) 213:11 226:22 offered (1) 201:7 offering (5) 14:7 15:24 16:5 227:5 227:10 office (1)	29:7 official (1) 123:23 officially (1) 31:11 oh (17) 46:4 48:6 51:2 65:22 92:5 94:23 100:18 100:18 133:8 156:8 156:11,20 160:10 199:9 200:7,13,22 Ok (2) 130:9 131:12 okay (124) 8:9 9:11 12:22 13:5 13:18 15:5 16:13 17:3 22:3,5,23 23:18,19,22 24:8 25:22 26:2,4 28:11 29:3 33:4,18 34:15 35:11,15 41:7 43:17 45:7 47:4 60:6,15 62:2 63:5,16 64:13 67:19 70:20 72:15 75:21 76:2 77:11,15 77:20 80:9 82:18 84:5 90:10 94:6 97:6,16,20,23 99:7 99:20 100:25 102:11,24 103:23 106:3 107:16 108:9 112:25 113:18 114:23 117:5,14 118:19 121:16,24 122:19 124:16 126:16 127:18 128:2 130:20 132:14 134:10 135:4,15 136:10 138:9 141:25 144:11 145:17,21 146:2 152:6,11 163:5,11,13,16,17 163:22 165:8,19 167:8,20 168:25 169:5 172:14 173:25 175:11 189:9 191:9,21 194:16 195:9 201:20,23 202:20 203:6,14 213:20 214:18 217:18 218:13 221:5,11,19 225:13 227:19 228:14 229:16 Okonedo (4)	2:18 7:5,5 156:14 old (1) 44:5 Oliver (1) 126:19 Olmsted (1) 199:4 once (7) 32:14 89:16 134:21 138:17 140:11 141:7 172:9 ones (7) 41:23 54:11 57:9 63:6 111:4,5 112:12 open (4) 19:16 189:13 193:5,8 opened (1) 10:13 operate (2) 29:8 171:11 operating (17) 9:21 10:18 35:22 72:6 79:4 109:14 120:25 178:25 186:4,23 199:18 206:14,19 206:22 214:16 216:4,9 operation (19) 36:4 46:17 63:23,25 64:3 96:23 115:18 115:19,20 117:21 118:2 184:25 189:5 189:13,20 193:2,10 206:8 217:23 operations (8) 10:19 52:9 57:6 61:24 62:3 126:7 189:23 190:12 operative (2) 87:10 206:4 opinion (13) 190:16,17 191:3,10 191:15 194:21 196:2 205:6,13 206:11 207:9 210:9 216:18 opportunistic (2) 25:21 44:21 opportunity (3) 75:14 82:21 87:7 opposed (4) 76:25 96:11 150:19 197:24 option (1) 131:18 options (2)
---	--	---	---	--

130:13 131:13 oral (1) 94:8 orange (1) 121:14 order (28) 8:4 13:16 14:21,23 15:3 16:20 17:5 18:2,19 26:5 37:19 37:23 38:2 40:9,13 41:3 69:21 87:4 150:19,20 155:16 156:21,23 164:20 171:3 194:25 195:12 227:12 ordered (1) 18:5 orders (1) 195:12 organization (1) 9:15 organizations (2) 174:2,7 original (1) 136:8 orthopaedic (28) 7:25 8:3 11:7,10,16 22:15,16 26:10 50:3 75:8 134:22 158:18 168:6 169:8,18,19 174:3,4,11,21 175:5 177:3,15 185:4 195:16 208:10 226:24 227:6 orthopaedics (15) 8:12 11:9,10,15 76:4 168:5,8 169:3,9,16 171:10,12 173:8 219:25 220:5 orthosurgeons (1) 141:14 outcome (4) 39:9 112:11 211:21 231:11 outcomes (2) 52:10 181:7 outlier (1) 66:8 outline (2) 135:17,24 outside (3) 33:6 37:18 74:19 overall (1) 11:6 overexaggeration (1) 153:21	overlap (1) 99:6 Overspeaking (1) 66:14 <hr/> P P (3) 107:18 203:6,8 p.m (8) 6:7 95:16,18 122:9,11 160:21,23 229:24 package (1) 152:19 page (100) 4:21 5:4 15:12 19:18 19:20 21:10 23:11 40:6,19 43:9 45:17 46:3 48:4,10,15 49:18 53:15 55:5 57:12 58:2,6 59:6,9 61:11,20 65:18,19 65:22,24,25 68:12 70:23 72:4,9 73:10 75:2,3,7,23 76:9,13 76:16 92:25 96:17 96:21 100:7,20,22 100:23 101:12,16 101:25 104:12,16 105:22 107:6,7 109:25 110:9 122:15,20 124:8,22 126:11,18,24 127:19 129:21 133:10 134:18 135:18 136:19 139:23 142:2 144:13 146:17 148:21 156:2,13,16 164:25 197:20 198:12 200:7,11,15 200:15 203:17 212:3,4,6 214:12 219:3 221:6,7,22 225:7,10,24 230:7 Page/Line (1) 232:5 pages (17) 14:18 16:4,5,25 22:25 23:20 52:17 53:6 55:11,22 57:14,22 64:12 86:22 127:18 230:5 231:5 paginated (9) 17:11 20:2,14,18,20 21:4,6 54:11 156:9 pagination (3)	15:22 16:12 19:22 paid (3) 61:16,18 222:20 pain (1) 118:4 pajamas (1) 109:8 panel (2) 222:17,18 paper (117) 21:18 23:3,4,22 30:9 30:22 31:12,19,20 31:24 32:2 34:12 42:23 43:21,23 44:4 44:5,6 46:25 47:24 53:5 69:12 71:14 72:2 73:3 82:13,15 82:16,17,20,22,24 83:7,8,9,10,15,18 84:3,3,6 86:9,19 87:8 88:14,19 89:15 90:24 92:16,25 95:9 96:15,18 99:22 101:16 106:19,25 107:3,8,9 108:6,7 109:21,24 110:25 116:10 119:23,25 120:6 122:24 123:24,25 124:2,3 124:13,24 127:3,8 127:11,19 128:3,12 128:16,19 129:8,9 129:10 131:25 143:24 146:12 147:24,24 149:20 151:11 152:8,17 153:2 197:24 198:4 198:8 199:5 210:24 212:19 214:3 215:16,18,21,22 219:18 228:6,8,14 228:16,20,23 229:2 229:15 papers (11) 31:14 109:23 124:4 132:7 136:14,16 147:18 165:23 177:19 191:17 194:5 paragraph (14) 17:7,13 40:25 65:19 65:25 68:25 96:21 102:6 104:15 110:12 123:3 195:14,23 196:8 parallel (1)	13:9 paramount (2) 181:13,16 Park (1) 3:12 part (24) 25:7 37:23 41:2 42:24 69:20 74:23 87:3 116:22 117:15 144:6 158:14,25 165:11 168:3 169:6 175:4,6,6 191:24 195:24 211:21 219:23 220:20 221:21 part-time (1) 46:15 participate (1) 128:4 particle (3) 187:12 192:16 209:2 particles (19) 21:21 175:24 186:24 187:11 192:25 193:6 206:18 207:24 208:2,2,4,17 208:20 209:13,20 209:21 211:6 214:9 216:9 particular (16) 16:2 21:16 22:4,14 34:5 35:20 36:17 42:6 45:9 78:15 114:17 120:25 124:21 128:16 136:15 142:16 particularly (4) 32:13 34:25 125:22 148:11 parties (6) 6:22 18:4 227:13,17 231:9,10 parts (1) 162:15 Parvizi (1) 174:24 pass (2) 79:25 171:4 patient (21) 36:3 56:2 58:18 76:20 86:7 110:4 149:12 153:8,23 179:10 181:11,14 185:16 186:5 188:11 189:23 193:12,14 193:17 217:15	224:12 patient's (2) 150:8 153:4 patient-warming (1) 39:22 patients (61) 36:6,21 37:2,4,6,8,8 37:13 46:10 47:6,10 52:10 62:14,22 76:21,22 85:8 86:13 89:11 90:13,13,18 91:2,3 94:10 98:14 99:15,16,20 102:15 102:17 105:24 113:24 114:15,19 115:3,4,12 116:8 117:10 120:8,21 125:13 153:5 159:12 182:20 189:20 190:5 193:17,20,23,23 198:5 202:5,6 215:12 217:2,22 218:9 223:11 224:4 Paul (15) 24:9 30:3 122:21 123:21 133:11,14 133:19 134:9 135:11,25 144:14 146:20,22 157:2 207:14 pause (1) 163:19 pay (1) 170:10 payroll (1) 124:6 PDF (1) 165:4 peer (13) 165:19,23,24 166:3 166:12,17 177:11 178:15,17 179:25 180:2,18 204:2 people (28) 29:22 31:4 60:21 67:4 69:16,16 70:2 71:2 109:2,9,10 116:15 117:21 147:10 151:17 157:16,16 157:17,18 173:13 173:14 176:8 180:4 188:20 189:2 194:6 212:24 217:19 people's (2) 157:7,14
---	--	---	---	---

<p>percent (27) 66:6,6 77:9 80:17 88:6,6 104:17,18,20 105:2 106:14,17 107:17,17,23,24 108:9,9 124:15 149:4 189:18 190:22,23 191:8 208:5,16 209:20</p> <p>percentage (1) 182:16</p> <p>Perfect (1) 101:13</p> <p>perfectly (2) 139:11 155:14</p> <p>perform (1) 9:23</p> <p>performed (4) 45:23 58:12 59:24 79:4</p> <p>performing (2) 54:23 69:22</p> <p>peri (2) 184:22,24</p> <p>peri-prosthetic (27) 175:9,13 177:17,23 178:2,22 179:2,5 182:8,24 183:17,20 184:6,16 185:8 187:22 188:12 210:17 214:15 216:7,14 217:17 219:15 226:24,25 227:7,8</p> <p>perilously (1) 205:5</p> <p>period (97) 8:7 29:13 45:9,24 46:21,24,24 47:19 47:20,20,23 50:6,16 51:4,12 55:3 59:20 63:18 64:5 66:21 67:25,25 78:10 79:4 82:25 83:14,18,21 87:11 88:11,15,22 89:10,19,23 90:2,11 90:18,21 91:2,6,9 91:10,13,15,16,19 91:20,24,25 92:3,15 93:11,25 95:25 97:3 97:8,9 98:13,16 99:3,11,14 102:14 102:15,19,25,25 103:5,7,17 104:24 104:25 105:5,6,15 105:25 106:9,12,16</p>	<p>108:2,11,25 114:24 118:17 119:18,23 121:20,21 152:15 184:17 188:23 191:20 201:12 204:6 210:20 217:3</p> <p>periods (4) 47:18 97:24 99:8,10</p> <p>perioperative (5) 76:24 184:17 217:3 225:19 226:6</p> <p>permanent (1) 121:24</p> <p>permission (4) 22:3 23:17 24:17 143:3</p> <p>person (5) 32:18,20 127:14 159:5 208:11</p> <p>person's (1) 137:10</p> <p>personal (1) 210:9</p> <p>personality (1) 27:16</p> <p>personally (4) 136:15 175:2 199:11 224:24</p> <p>persuaded (2) 42:9,11</p> <p>phase (2) 25:4 90:22</p> <p>philosophy (2) 184:20 185:3</p> <p>phone (1) 201:25</p> <p>photo (1) 71:5</p> <p>photograph (4) 71:12,18,23 72:18</p> <p>physician (2) 7:19,23</p> <p>physicians (1) 170:25</p> <p>pick (3) 130:13 131:13 166:2</p> <p>picked (1) 95:6</p> <p>picking (1) 105:13</p> <p>picture (8) 54:8 72:13,14 120:12 140:4 166:24,24 167:18</p> <p>pictures (1) 139:25</p>	<p>piece (6) 71:21,21 120:9 136:8 151:8 190:3</p> <p>pieces (1) 166:3</p> <p>Pilgrim (2) 6:5,15</p> <p>pilot (11) 5:8 159:9 160:6 219:23,25 220:20 221:16 222:2 224:14 225:10,11</p> <p>pin (1) 93:6</p> <p>pitched (1) 33:11</p> <p>PJI (6) 178:3,3,13 181:7,20 210:4</p> <p>PJIs (6) 178:8 179:16,19 181:5 194:6 214:23</p> <p>place (4) 68:14 69:2 84:14 178:4</p> <p>placed (1) 142:10</p> <p>places (2) 32:14 110:24</p> <p>plaintiffs (14) 3:8,14 6:25 7:3 17:10 20:17 48:25 49:3 100:7 128:25 155:17 161:3,8,14</p> <p>plan (1) 25:15</p> <p>planned (5) 25:17 61:6 63:2 158:9 158:10</p> <p>plates (2) 27:12,18</p> <p>plausible (2) 89:13 139:11</p> <p>playing (3) 70:16,19,20</p> <p>please (15) 6:21 33:18 122:15 133:9 162:24 163:6 163:7,9,24 164:5 169:13 191:11 200:24 212:10 213:21</p> <p>plenty (1) 189:2</p> <p>plots (1) 125:2</p>	<p>plus (3) 84:14 98:2 101:10</p> <p>pm (2) 183:9,11</p> <p>pneumonia (1) 87:21</p> <p>point (43) 27:2 28:10 34:17 37:24 39:8 40:2,18 40:24 43:13 46:20 47:9,13 63:21 66:19 69:2 80:25 81:2 87:15 89:25 103:23 103:25 104:7 111:16 112:20 113:23 115:8,11 117:11 118:11,22 120:24 125:24 140:24 144:7,10 159:24 182:2 188:20 201:11,23 203:8 211:5 224:10</p> <p>pointed (2) 59:6 63:17</p> <p>points (1) 44:10</p> <p>policy (1) 111:18</p> <p>poor (2) 58:24 67:15</p> <p>populate (3) 56:21 60:14,16</p> <p>populated (2) 60:11 64:6</p> <p>portal (2) 185:21,22</p> <p>position (2) 33:19 172:18</p> <p>positive (1) 31:24</p> <p>possibility (1) 103:8</p> <p>possible (4) 137:22,23 141:23 163:18</p> <p>possibly (2) 149:6 217:9</p> <p>post (1) 166:8</p> <p>post-operatively (1) 96:3</p> <p>posted (1) 141:14</p> <p>poster (1) 30:23</p> <p>posters (1) 32:4</p>	<p>potential (4) 21:19 33:2 40:20 137:22</p> <p>potentially (3) 26:15 123:9 182:4</p> <p>practice (10) 117:8 128:7 142:23 143:19 171:9,11 188:11 190:5 210:22 217:10</p> <p>practices (4) 39:23 80:19 195:17 211:5</p> <p>practicing (1) 10:15</p> <p>practitioner (2) 172:10,13</p> <p>praising (1) 133:19</p> <p>pre-marked (1) 13:20</p> <p>pre-selected (1) 50:2</p> <p>pre-warm (1) 116:15</p> <p>pre-warmed (2) 117:22 118:2</p> <p>pre-warming (10) 115:12,24 116:5,13 116:21 117:2,10 118:7 217:12,22</p> <p>pre-wash (1) 77:8</p> <p>precise (1) 119:4</p> <p>predictor (1) 152:21</p> <p>prefer (2) 43:17 49:5</p> <p>preference (2) 78:8 111:20</p> <p>preferred (1) 131:15</p> <p>preoperative (1) 217:3</p> <p>prep (3) 77:8 78:3 118:12</p> <p>prepared (5) 123:10 164:8,11,20 176:12</p> <p>preparing (2) 79:8,13</p> <p>present (8) 3:17 134:23 142:25 144:3 165:15</p>
---	--	---	--	--

<p>188:20 189:7 202:9 presentation (22) 30:17,20 31:2,7 32:4 33:25 75:19 132:23 134:7 135:17,25 136:2,3,11,18 138:4 141:23 142:15,16 143:2 174:11,16 presentations (7) 109:22 116:17,18 174:17,18,19 177:12 presented (4) 32:15 134:25 143:22 201:7 presenters (1) 135:24 presenting (1) 30:19 presents (1) 189:8 preserved (1) 65:3 press (1) 19:10 presumably (2) 31:2 126:9 presumed (1) 18:21 pretty (12) 26:5 32:15 36:21 103:14 113:9 118:24 128:17 155:15 157:20 173:20 207:8 229:15 preventing (2) 225:18 226:5 prevention (7) 12:8 13:13 68:5 77:3 77:6 160:11 222:14 prevents (2) 216:6,7 previous (3) 40:16 170:9,11 previously (2) 12:5 63:22 primaries (4) 125:7,17 126:2,3 primary (16) 29:3 31:6 45:22 96:23 120:17 124:2 126:4 126:5,6 188:13,23 189:5 196:17 198:14 211:21 226:8</p>	<p>principal (2) 49:10 158:10 principle (1) 91:19 print (2) 58:15 150:18 printed (3) 57:14,22 165:9 printing (1) 79:19 printout (2) 62:8,12 prior (13) 10:15,18 45:12 50:11 62:11,23 63:24 69:8 88:10 98:2 103:12 204:17 221:17 privy (1) 131:21 probabilities (1) 74:7 probability (2) 190:18 191:4 probably (56) 24:18 29:17 30:5 31:4 36:17 45:15 46:13 59:3,18 62:4 69:11 69:14 72:8 80:6 82:4 86:9 87:21 98:19 111:19 112:19 113:19 115:15 117:11,13 118:8 125:23 127:3 133:2 134:24 135:2 136:6,22 138:16,16 144:8 145:22 151:14 157:6,11,13 158:15 165:12 166:14,20 175:11 180:25 186:17 192:13 193:12 201:9 207:4 215:4 220:17 222:8 223:3 229:5 problem (2) 78:19 119:8 problematic (1) 188:8 procedure (4) 18:15,16,20 58:20 procedures (6) 45:23 70:12,13 79:3 116:22 119:19 proceed (1) 70:17 proceedings (3)</p>	<p>6:24 228:19 230:6 process (5) 12:18 60:19 63:8 178:17,18 produce (1) 184:8 produced (9) 17:19 39:25 52:7 55:8 55:9 81:10,15 141:13 166:5 produces (1) 152:25 product (2) 27:9 162:3 production (2) 191:17 213:5 Products (2) 1:5 6:11 professional (2) 7:13 149:11 Professor (6) 27:5 28:12 29:22 33:14 158:20,22 progenitor (1) 25:22 program (7) 8:25 173:4,10,21,23 177:4,6 progress (1) 71:12 project (3) 29:16 30:4 221:16 prolific (1) 199:10 prominence (3) 123:8,15,20 prompt (1) 177:9 proof (1) 54:7 proper (5) 42:15 48:17 98:11 130:19 195:20 properly (1) 78:16 prophylactic (3) 85:2,2 179:15 proportion (3) 85:7 182:16 189:18 proposed (1) 31:2 prospective (2) 44:20,23 prospectively (1) 44:18 prosthetic (1)</p>	<p>181:9 protect (1) 184:9 protected (1) 185:14 Protection (2) 67:2,7 protects (1) 87:22 protocol (6) 204:16,16,19 205:2 220:8,14 protocols (2) 110:17 204:12 proven (2) 88:2,3 provide (2) 167:17 176:3 provided (9) 13:22 16:7,10 17:11 53:2,6,13 96:3 197:21 provides (1) 18:3 providing (2) 12:15 201:4 proxy (1) 116:16 publication (7) 23:12 30:17 32:3 72:7 72:15 145:3 180:7 publications (5) 164:25 165:10 177:11 177:13 190:14 publicized (1) 176:6 publicly (2) 67:13 119:15 publish (2) 63:10 151:11 published (24) 21:25 23:7,8 24:15 41:4,23 42:2,3,4 92:18 116:7 122:24 128:3 152:8 202:23 208:3 213:6,7,9,11 213:15,16 216:24 224:8 publishing (1) 148:7 PubMed (8) 165:6,18,21,22,22 166:8,11,14 pull (1) 52:4 pulled (3)</p>	<p>53:2 153:24 213:4 pulling (3) 63:14 149:6 151:12 purely (1) 45:5 purple (1) 109:7 purpose (3) 109:5 181:10 218:4 purposes (3) 15:7 17:4 44:25 pursuant (2) 16:8 55:9 pushed (3) 148:14,16,16 pushing (1) 41:13 put (38) 14:4 15:5 16:13,14 17:15 18:11,14 19:6 33:12 44:3,4 62:17 62:18 64:24 80:20 81:6 92:16 108:6 119:23 128:13,19 129:7 132:15 136:14 148:10 151:17 163:19 164:19 179:10,11 195:20 197:6 201:6 201:7 210:23 215:24 218:11 219:19 puts (1) 67:9 putting (2) 41:6 224:16</p>
Q				
<p>Q4 (1) 121:18 Q4/2010 (1) 118:18 qualification (3) 169:10 170:17 171:13 qualifications (1) 169:14 qualified (7) 40:25 167:21 170:6 170:15,16,20 171:20 quality (8) 11:11 12:6 13:14 58:15 180:11,11,12 199:17 quarter (10) 46:17 63:22 64:6</p>				

113:15 117:13 118:25 121:10,10 121:11 193:13 quarters (1) 66:2 quartile (1) 63:25 Queen's (1) 6:12 question (54) 16:14 33:12 35:5,8 38:18,21 39:12,18 46:5 52:4 56:10,12 58:11 66:15 69:7 74:12,14,22 79:9 80:10,14 110:23 114:4,7 130:21 134:10 135:4 138:8 138:22 142:11,22 142:24 143:7 145:18 162:16,24 163:3,4,20 189:4 191:12 194:23 195:20 198:10 205:4,21 206:2 209:24 210:5,10 218:16 222:21 225:5 229:13 questioned (1) 17:10 questioning (3) 42:14 72:11 174:10 questions (17) 43:12,16 54:6 64:19 69:20 70:21 76:13 139:15 141:19 143:14 162:23 163:10 190:15,24 194:25 227:2 228:7 quickly (2) 120:14 155:15 quite (22) 34:7 39:7 58:25 82:4 82:5 113:3 128:19 129:7,8,13,15 136:25 149:5,19 167:25 170:25 177:19 179:12 181:8 182:13 193:3 198:8 quote (2) 67:11,13 quotes (1) 67:13 R	R (243) 1:1,12 2:1 3:1 4:1,6 5:1 6:1,3 7:1,9 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 21:1 22:1 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 36:1 37:1 38:1 39:1 40:1 41:1 42:1 43:1 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1 52:1 53:1 54:1 55:1 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1 71:1 72:1 73:1 74:1 75:1 76:1 77:1 78:1 79:1 80:1 81:1 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1 96:1 97:1 98:1 99:1 100:1 101:1 102:1 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1 116:1 117:1 118:1 119:1 120:1 121:1 122:1 123:1 124:1 125:1 126:1 127:1 128:1 129:1 130:1 131:1 132:1 133:1 134:1 135:1 136:1 137:1 138:1 139:1 140:1 141:1 142:1 143:1 144:1 145:1 146:1 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1 162:1 163:1 164:1 165:1 166:1 167:1 168:1 169:1 170:1 171:1 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1 180:1 181:1 182:1 183:1 184:1 185:1 186:1 187:1 188:1 189:1	190:1 191:1 192:1 193:1 194:1 195:1 196:1 197:1 198:1 199:1 200:1 201:1 202:1 203:1 204:1 205:1 206:1 207:1 208:1 209:1 210:1 211:1 212:1 213:1 214:1 215:1 216:1 217:1 218:1 219:1 220:1 221:1 222:1 223:1 224:1 225:1 226:1 227:1 228:1 229:1 230:1,5,23 231:1,5 232:1,3,3,4 232:24 radar (1) 162:6 raise (1) 141:18 raised (2) 77:25 211:14 ran (1) 204:10 random (3) 35:16,23 36:5 randomized (25) 34:18,24 35:14,15,21 36:2,7,9,11,12,13 36:14,19 37:2,15 38:13 39:2 41:14,16 158:4 159:6,8 161:25 162:2 225:2 randomizing (1) 159:11 rank (1) 173:15 ranks (1) 170:14 rare (4) 39:9 187:25 190:9,11 rarely (3) 180:9 182:2 214:17 rate (17) 69:13 97:17 102:24 104:17,19 105:2 106:14,16 108:10 159:13,15,17 193:3 204:11 217:20 223:23 228:4 rates (48) 45:5 46:18,20 63:11 66:4,23 67:10,14 68:2 71:9 78:22,25 85:22,24 86:11,11 87:19 92:18 104:6	106:20 112:12,14 115:7 116:20 118:5 118:8 119:13 120:3 120:7,8,15,16,18 152:12 157:20 158:7 198:19 202:15 204:20 210:21 211:19,24 215:11,17,23 217:22 218:3 223:12 ratio (4) 218:23,24,25 227:25 rationale (2) 94:11,13 ratios (1) 229:3 RBC (1) 104:18 RCT (3) 157:8,25 160:2 RCTs (1) 194:4 re-examination (1) 227:21 reaching (3) 157:7,14 180:14 read (29) 23:8 58:18 66:9,16 79:17,24 80:2,3,5,6 87:7 104:22 116:19 122:25 123:4 125:2 129:9,12 132:25 133:2 138:15,16,18 146:24 180:5 204:13 212:17 225:20 230:5 reading (8) 43:19 45:25 66:18 88:8 112:22 130:23 147:2 225:21 reads (1) 124:24 real (3) 7:23 18:8 123:8 reality (1) 107:21 realized (3) 14:8 15:3 176:16 really (16) 7:22 18:12 47:18 58:15 59:13 64:10 69:25 111:5 128:13 130:6,7 142:25 144:2 151:10 157:3 210:6	reason (14) 13:10,10 34:23 49:10 49:10 68:12 85:4 109:24 128:14 145:4 191:5 228:25 229:3 232:5 reasonable (5) 108:16 190:18 191:3 215:5 226:7 reasonably (1) 159:5 reasoning (1) 63:18 reasons (1) 148:5 reassuring (1) 33:10 recall (16) 30:3 51:22 66:21 72:15 74:12 75:10 75:11,16 78:10 134:25 138:3 144:16 146:25 147:2 204:7 211:17 receipts (1) 135:12 receive (1) 144:17 received (8) 14:17,18 67:17 134:15 176:17,19 177:2,4 receiving (4) 66:6 72:19 91:2 102:15 recognition (1) 170:5 recognize (2) 75:24 151:22 recognized (1) 8:14 recollect (3) 26:4 30:2 206:25 recollection (25) 22:22 24:25 25:10 28:18 63:20 67:16 68:10,20 104:5 113:21 116:8 118:15 127:9,22 128:16 135:12,14 140:10 142:17 147:6,23 196:20 200:25 203:8 208:6 record (50) 6:9 14:2,4 15:6 16:13 16:14 17:5,15 18:11
--	--	--	---	--

18:14 19:7 21:9 40:8 54:16 56:8 57:5 66:18 76:10,14 76:14 81:6,22 95:14 95:21 122:7,8,12 130:17 150:21 154:24 155:5,6 160:19,20,24 163:15,19 183:4,7 183:13 190:11 197:4 198:12 212:16 214:13 215:6 221:12 225:9 229:23 231:7 recorded (1) 231:6 recruit (1) 224:4 recruited (1) 158:14 recruiting (1) 224:3 Rectal (1) 94:21 red (2) 71:3 118:18 reduce (16) 67:25 73:22 78:22 85:22 114:16 118:8 119:13,14,16 178:22 179:2,5,16 179:19,20 190:25 reduced (4) 86:13,16 112:14,15 reduces (9) 115:7,20 120:7 182:6 216:9 217:16,19,22 218:2 reducing (10) 71:8 73:14 78:25 85:24 118:4,4,4,5 219:24 220:4 reduction (9) 83:24 86:12 116:20 123:5,7,14,20 204:3 204:11 reductions (1) 80:17 Reed (319) 1:1,12 2:1 3:1 4:1,6 4:21,23 5:1,3,4,5,5 6:1,3,10 7:1,4,5,8,9 7:14,18 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1,7 17:1,9 17:22 18:1,6 19:1	19:14 20:1,7 21:1 22:1,4 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 36:1 37:1 38:1 39:1 40:1 41:1,13 42:1,17 43:1,11 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1 52:1,19 53:1,23 54:1,8 55:1 55:17 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1,23 71:1,23 72:1 73:1,12 74:1 75:1,7 76:1 77:1 78:1 79:1 80:1 81:1 81:5,7 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1 95:14,20,24 96:1 97:1 98:1 99:1 100:1 101:1,6 102:1 102:2 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1 116:1 117:1 118:1 119:1 120:1 121:1 122:1 122:16 123:1 124:1 125:1 126:1,19,22 126:25 127:1,5,20 128:1,12,19 129:1 130:1,14 131:1,14 132:1 133:1,11 134:1,14 135:1,25 136:1 137:1 138:1 139:1,9 140:1 141:1 142:1 143:1 144:1 145:1 146:1,19 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1,2 162:1 163:1 164:1,3 164:5 165:1 166:1 167:1 168:1 169:1 170:1 171:1 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1 180:1 181:1	182:1 183:1,7,13,16 184:1 185:1 186:1 187:1 188:1 189:1 190:1 191:1 192:1 193:1 194:1 195:1 196:1 197:1,15,19 198:1 199:1 200:1,9 200:16 201:1 202:1 203:1,11,16,19 204:1 205:1 206:1 207:1 208:1 209:1 210:1 211:1 212:1,4 212:7,7,8 213:1,22 214:1,14 215:1 216:1 217:1 218:1 219:1,3 220:1,7 221:1 222:1 223:1 224:1 225:1,10 226:1,12 227:1,24 228:1 229:1,20,23 230:1,5,23 231:1,5 232:1,4,24 refer (10) 22:3 23:17 24:17 46:8 59:17 145:10 177:25 195:15 214:12 215:20 reference (15) 37:22 45:17 49:24 55:17 68:25 83:10 83:15 111:11 125:12 136:11 149:18 151:4 156:4 156:6 158:2 references (2) 42:15 125:4 referred (4) 108:7 171:20 184:22 198:21 referring (13) 81:4 82:16 96:18 105:18 123:16 134:9,17 140:21 149:9 197:23 198:3 218:5 220:2 refers (8) 16:20 55:18 61:21 127:24 132:5 146:2 146:11 157:10 reflected (1) 84:10 reflective (1) 120:15 refresh (1) 140:10 refusing (1)	154:19 refute (1) 207:13 regard (1) 164:16 regarding (8) 54:6 70:2 161:23 162:14 203:4 216:15 224:22,23 regardless (3) 94:13 155:17 229:8 regards (1) 56:4 regime (1) 84:10 regimen (9) 89:18 90:11 91:3,14 92:9 98:15,15 106:9 106:10 regimens (1) 103:6 regimes (1) 205:17 region (4) 171:14,15 173:18 208:5 registered (1) 196:4 registrar (4) 172:5,6,8,20 registrars (2) 172:25 173:18 regularly (1) 66:6 regulated (2) 169:24,24 reimbursed (1) 135:13 rejected (1) 32:17 relate (8) 42:4 70:9 79:20 80:10 118:6 172:14 177:20 191:18 related (5) 13:9 34:9 135:3,6 194:22 relates (5) 40:3 41:22,25 70:8,10 relating (1) 41:22 relation (4) 17:9,20 139:6,10 relationship (1) 40:3 relative (5)	219:7,13,14 231:9,10 relatively (2) 37:5 187:25 relevance (1) 149:21 relevant (4) 42:10 45:20 87:10 143:5 reliable (3) 61:14 64:4 149:4 reliably (1) 149:13 rely (7) 18:16 40:9,15 52:12 52:13 61:18 62:5 remain (1) 190:3 remainder (2) 89:18,22 remained (1) 89:22 remarks (9) 21:9 54:16 122:7 150:21 154:24 214:13 215:6 221:12 225:9 remember (24) 53:10 72:17,17,19,21 74:2,4 96:9 112:12 112:15 114:6 118:17 134:5 149:10 152:9 159:3 174:9,13,14,16 177:8 200:23 223:23 228:3 remind (2) 84:6 141:13 reminded (1) 148:16 reminding (1) 148:17 remotely (1) 214:6 removal (1) 189:10 remove (3) 189:21,24 190:6 removed (3) 60:22 62:16,17 renal (3) 85:4 86:11 87:22 repair (3) 66:5 78:11 79:5 repaired (1) 121:6 repeat (7)
---	--	--	---	--

7:8 11:25 16:18 56:12 85:19 105:12 175:10 rephrase (1) 185:18 replace (2) 10:16 189:24 replacement (25) 9:3 23:6 45:22 46:10 58:21 60:9,25 61:6 62:18 82:11 105:4 120:8,18 126:4,6 168:10 175:14 178:5 181:6 188:21 189:3,11 193:10 212:25 218:2 replacements (5) 54:24 60:22 104:21 121:19 181:11 reply (1) 44:2 report (1) 52:7 reported (2) 104:20 105:3 reporter (4) 6:19 163:15 231:2,4 reporting (3) 6:18,20 66:4 represent (2) 6:22 161:3 represented (1) 174:20 representing (3) 161:7,13,17 required (4) 78:11 87:23 169:15 194:25 requirements (2) 13:24 16:8 research (21) 8:14,23 30:19 31:18 32:8 36:7 134:15 136:8 144:22 159:2 168:6 178:22,25 179:4,15,18 181:5 208:25 209:5 210:7 218:15 researching (1) 183:3 reservoir (2) 185:21 186:4 residency (9) 8:8,10,10,11,20,21,22 172:16,21 resident (1)	172:20 resistant (1) 113:25 resistive (2) 223:6 225:16 resource (1) 149:7 respect (28) 11:6 33:20 37:20 41:6 41:12,20 80:13 108:12 139:8 152:7 161:4,8,14,18 174:3 181:14 182:23 185:25 187:22 196:16 204:4,6 205:21 211:15 215:10 216:12 226:23 227:6 respond (2) 42:5 140:22 responds (1) 140:17 response (4) 67:21 139:17 141:20 164:20 responsibilities (2) 11:6 13:11 responsive (2) 140:12,18 rest (1) 8:24 restrict (1) 196:8 restricted (3) 18:17 38:19 39:23 result (5) 166:5 184:13 209:4 210:7 213:2 resulted (1) 57:9 resulting (1) 80:17 results (7) 27:21 31:9 32:9 33:23 141:19 203:7 226:16 retrospective (1) 44:16 return (11) 87:24,24 88:3 92:17 152:12 188:23 211:17,22 214:21 215:9,13 returned (1) 214:16 returning (2)	94:18 214:25 reveal (1) 187:23 reverse (1) 150:19 review (14) 12:25 16:9 37:25 140:11 141:22 178:15,17,20 179:25 180:2,18,25 204:2 218:12 reviewed (9) 60:12 165:19,23,24 166:4,12,17 177:11 181:3 reviewer (3) 177:13 180:22,24 reviewers (3) 124:24 151:10,20 revision (4) 120:20 168:10 198:17 198:19 reword (1) 145:18 rewording (1) 210:10 Richard (1) 7:14 rid (4) 184:10,12 185:10 189:16 riders (1) 82:20 right (104) 8:19 12:10 19:22 20:21 25:24 46:13 46:25 48:14 50:10 50:25 51:3,5,13,14 54:5 55:23 58:4,19 62:4 68:21 77:3,6,7 77:10 79:14 80:25 81:2 82:18 83:9,22 84:4 87:11 88:8,11 88:18 89:23 90:19 90:25 91:11,18,22 91:23 92:9 93:9,12 93:13,14,22,25 94:16,23 97:14,19 97:22 98:16,19 99:8 99:9 100:10 105:8 106:2,6,18 107:9 108:23 112:23 113:20 118:12,15 118:16,19 119:22 121:15 122:24 123:2 129:18 131:7	135:18 140:19 146:4 147:25 160:16,19 164:12 166:18,20 167:7,12 167:20 169:17,25 171:11 176:3 177:10 186:20 193:18 196:18 200:25 202:21 212:12 225:24 226:21 228:18,18 rigorous (1) 178:18 RHO (4) 5:8 220:3,4,4 risk (11) 45:21 52:9 61:4 76:19 110:4 153:9 175:12 219:4,7,13,14 rivaroxaban (40) 5:7 92:15,20,22 93:8 93:11,17,19,22 94:3 94:14,16 95:25 96:2 96:19 97:3,22 98:3 98:22 99:4 101:11 103:17 104:2,11,19 104:25 105:5,15 106:4,13,15,19,23 106:24 107:3 120:2 152:3,8 212:20 213:2 road (1) 13:8 Robert (1) 146:19 robust (1) 151:16 rogue (1) 206:25 role (3) 131:17 144:22 145:4 room (11) 79:4 80:4 186:4,23 206:15,19,22 207:14 214:16 216:9 227:19 rooms (2) 199:18 216:4 root (1) 118:23 Rose (4) 1:24 6:19 231:4,23 rough (2) 123:23,25 round (3) 148:18 174:22 175:20	route (3) 22:10 82:23 189:22 routine (2) 78:20 116:22 routinely (2) 45:2 143:7 RTT (1) 88:2 rule (1) 15:18 rules (12) 16:21,21 18:18 69:16 131:5,6 162:22 169:17,18 191:6 226:22 227:9 ruling (3) 18:9 74:11,13 run (3) 158:13 203:3 222:14 running (5) 12:16 13:8 58:14 150:19 164:21 runs (2) 12:16 21:15 <hr/> S <hr/> S (1) 148:23 S-E-S-S-L-E-R (1) 198:25 safe (1) 208:21 safer (2) 181:11 215:24 safety (2) 181:13,16 sake (1) 79:18 salutation (1) 33:20 sample (1) 37:24 San (3) 134:14,21 174:12 sat (2) 168:2,13 save (2) 101:12 118:16 saw (19) 26:5 62:8,12 64:15,16 72:16 75:11 134:15 137:15 138:14 139:6,9 141:20,21 144:17 147:11 176:24 200:19 224:17
---	--	--	---	---

<p>saying (25) 31:20 32:5 53:20 61:14,19 66:17 82:24 87:4,14 98:9 98:21,23 100:18 105:13 107:18 108:16 124:9 126:9 142:4 151:11 152:5 158:3 190:21 202:2 228:17</p> <p>says (22) 44:3,4 53:21 59:11 65:19 68:12 75:7 96:7,22 102:8 104:16 106:3 119:3 134:13 137:5,18 144:20 146:21 200:13 208:13 215:18 225:15</p> <p>Scaffidi (2) 3:17 6:17</p> <p>scale (1) 36:20</p> <p>Scarborough (3) 158:20,23,25</p> <p>schedule (7) 39:20 40:11,12,19 41:19 74:23 196:9</p> <p>scheme (2) 168:4,7</p> <p>Scholar (11) 165:7,8,10,12,14,17 165:25 166:5,10,16 178:21</p> <p>school (5) 8:15,17,18 19:9 167:7</p> <p>science (1) 31:18</p> <p>scientific (2) 217:14 222:18</p> <p>scope (11) 37:18 38:9 40:19 41:18 73:2 74:19 87:3,4 90:6 194:24 195:8</p> <p>score (3) 152:21 153:4,8</p> <p>scoring (3) 150:15 152:20,25</p> <p>Scotland (2) 9:7 171:19</p> <p>Scots (4) 170:15,16,20 171:20</p> <p>Scott (13) 123:22 124:5 130:9 131:12,22,22</p>	<p>133:12 135:6 144:15 146:21 148:23 156:25 224:9</p> <p>screen (1) 143:11</p> <p>screening (11) 113:24 114:5,9,10,11 114:13,20 115:4,5 120:4 190:25</p> <p>scribble (1) 98:8</p> <p>scribbles (1) 48:22</p> <p>scrub (4) 77:9 186:11 189:14 207:6</p> <p>scrubs (1) 109:7</p> <p>sealed (8) 14:20,23 15:3 16:20 37:19,23 69:21 87:4</p> <p>seams (1) 153:22</p> <p>search (2) 166:9,12</p> <p>searches (2) 166:6,10</p> <p>second (11) 14:16 35:13 40:19 42:24 47:19 76:23 117:13 123:3 168:3 200:11,15</p> <p>secondary (1) 145:4</p> <p>secondment (1) 69:4</p> <p>seconds (1) 227:21</p> <p>section (1) 44:11</p> <p>secure (1) 38:23</p> <p>see (33) 18:15 23:10,13 27:12 36:11 44:22 48:6 57:16 58:15 75:8 93:6 98:7 100:18 113:5,7 132:15 134:14 139:13,17 145:18,24 150:4 159:10 165:2 177:2 184:25 202:9,15,24 206:22 214:6,21 225:21</p> <p>seeing (5)</p>	<p>72:15 75:10 103:9 144:16 146:25</p> <p>seeking (1) 87:9</p> <p>seen (30) 33:5,7 38:2 64:14 72:16 75:12 115:23 116:13,14 126:8 131:19 137:14 139:20 141:6,7,7 144:23 147:12 158:15 176:11,13 189:2 200:18 203:12,22 220:8,12 220:13,13 221:13</p> <p>selected (1) 174:22</p> <p>sells (1) 181:17</p> <p>send (8) 30:10,13 147:20 148:4 180:2,3,3,8</p> <p>sending (1) 200:23</p> <p>sends (1) 134:11</p> <p>senior (12) 7:19 8:11,21,25 17:16 22:13 24:13 40:10 65:13,15 69:23 195:24</p> <p>sense (3) 44:20 111:13 139:10</p> <p>sensitive (1) 114:3</p> <p>sent (6) 40:13 123:19,21 127:3 137:12 200:6</p> <p>sentence (2) 125:15 201:15</p> <p>separate (5) 62:21 101:3 136:13 140:15,17</p> <p>separately (3) 34:7 81:5 152:14</p> <p>separation (1) 24:24</p> <p>September (8) 51:7 59:4,25 60:4 88:23 89:7 93:20 220:10</p> <p>sequence (3) 35:12 95:5 137:4</p> <p>sequentially (4) 55:7 140:19,21,22</p> <p>series (5)</p>	<p>54:20 103:14,18 194:8,9</p> <p>serious (3) 119:7 124:10 181:20</p> <p>SERJEANTS (1) 2:11</p> <p>serve (2) 11:17 12:14</p> <p>served (3) 12:5,19 17:22</p> <p>service (1) 172:11</p> <p>Services (2) 2:16 75:17</p> <p>Sessler (7) 198:22,22 199:2,4,11 218:13 225:4</p> <p>set (6) 21:6 25:20 26:24 54:12 70:3,13</p> <p>set-up (1) 23:24</p> <p>sets (2) 150:9 151:12</p> <p>seven (21) 34:8 48:13,14 51:3,6 51:9,10 90:10 93:11 93:21,24 94:14 95:3 96:25 97:10,21 98:15 103:2,6,21 106:15</p> <p>Seventh (1) 2:22</p> <p>severity (2) 182:18,19</p> <p>share (1) 24:19</p> <p>shed (1) 208:11</p> <p>sheet (2) 30:24 100:2</p> <p>sheets (1) 58:14</p> <p>Sheffield (2) 8:23 168:6</p> <p>Shields (1) 10:21</p> <p>short (5) 64:23 108:2 152:15 166:3 172:21</p> <p>shorthand (1) 231:6</p> <p>show (18) 33:8 37:6,8 42:10 120:10 130:6 143:4 143:10 158:5,16</p>	<p>194:10 204:23 209:6,11 210:11 211:23 223:13 226:19</p> <p>showed (9) 27:22 31:20 72:3 86:10 106:21 192:15 194:6 203:7 206:18</p> <p>showing (4) 16:25 152:19 205:8 227:25</p> <p>shown (3) 26:8 210:19 229:14</p> <p>shows (5) 32:2 116:14 125:23 126:18 149:2</p> <p>side (3) 43:21 110:12 112:23</p> <p>sides (1) 209:9</p> <p>sign (2) 75:14 128:8</p> <p>signal (1) 215:23</p> <p>signature (1) 147:16</p> <p>signed (5) 222:4,4 230:22 231:22 232:23</p> <p>significance (5) 87:20 106:22 107:19 108:19 204:19</p> <p>significant (14) 43:23 86:12,21 104:9 106:20 107:17 116:20 119:24 182:16 189:21 203:7,9 211:23 215:22</p> <p>significantly (2) 17:22 37:9</p> <p>similar (7) 104:20 105:3 110:4 158:17 160:14 190:19 203:25</p> <p>similarly (1) 214:5</p> <p>simple (1) 80:14</p> <p>simply (1) 42:15</p> <p>simulated (1) 23:6</p> <p>simultaneously (1) 24:22</p>
--	---	---	--	---

single (3) 15:12 84:15 208:8	144:5	198:2 200:13,22	159:18 195:22	29:14 45:4 73:17
sir (8) 17:4 23:15 41:20 48:24 49:13 70:20 107:9 195:12	slow (1) 188:4	202:14 225:8 227:3	227:11	stamp (2) 155:14 156:7
sit (5) 134:5 168:20,22 169:15 222:13	small (8) 59:3 103:14 108:17 108:18,18,19 112:6 132:19	sort (36) 8:4,14 13:16 21:21 23:3,24 24:25 25:3 25:9,22 28:18 30:22 35:3 36:20 52:13 60:8 63:7 68:9 107:20 108:25 109:7 142:20,22 143:9 148:10 153:20 154:16 166:9 168:14 173:16 176:6 184:19 193:9,10 205:18,24	specified (2) 110:21 195:13	stance (1) 24:14
site (19) 12:7,8,12 13:13 45:21 54:20 56:20 65:17 67:5 68:5 71:4 97:17 192:16 206:20 209:14 210:3,16 211:6 214:10	smaller (2) 35:2 159:17	so-called (1) 166:2	speculate (5) 127:15 133:22,22,25 163:10	stand (6) 11:21 30:21,24 54:21 226:12,20
sitting (1) 145:6	smoke (4) 26:7 33:7 76:22 141:13	sought (1) 38:12	speculating (4) 134:3,8 136:22 145:14	standard (7) 12:6 13:14 64:2 77:18 187:17,19 191:7
situ (1) 183:25	smokers (2) 194:2,3	sound (2) 165:11 166:18	speculation (4) 55:13 73:24 133:20 145:12	standing (3) 18:19 56:4 120:13
situation (1) 206:13	smoking (3) 194:16 195:5,19	sounds (5) 89:13 99:9 122:25 174:13 175:25	speculative (1) 127:15	standpoint (1) 107:23
situations (1) 159:18	so-called (1) 166:2	source (1) 186:15	speed (1) 112:20	stands (1) 220:4
six (27) 8:12,13 48:14 51:6 94:2,14 95:3 103:21 104:24,25 105:4,6 106:4,8,13 115:9 117:9 120:11 153:18 154:7,11 162:4 168:6 188:13 190:6 209:21,22	Society (13) 30:14,15,25 31:3,13 33:24 136:4 150:2 160:11 165:16 174:6 221:24 224:16	sources (1) 40:4	spelt (1) 198:24	staph (4) 59:11 60:6 114:3 120:7
sizes (1) 37:24	soft (1) 169:18	south (2) 2:22 136:4	SPENCE (1) 3:12	staphylococcus (2) 113:25 114:9
skills (1) 80:25	sole (1) 71:17	space (1) 19:15	spend (2) 24:18 140:8	start (17) 9:25 35:2 46:11 47:5 70:16 88:10,21 99:5 117:10 121:10 155:25 162:21 163:20 166:23 167:3 228:18,18
skin (5) 77:8 78:3 118:12 187:2 208:12	solely (2) 93:24 123:11	span (1) 182:7	spending (2) 18:12 155:9	started (10) 83:21 89:4 113:24 114:10,11 124:10 149:10 157:12 167:19,21
skip (1) 49:17	solicitor (1) 7:5	speak (6) 43:2 135:5 137:24 163:7 182:11,13	spent (4) 99:2 183:2 205:7 210:25	starting (4) 45:24 50:3 166:25 167:5
slide (7) 137:19 142:9,10 143:5,11,16,18	somebody (6) 72:25 114:13 128:7 130:23 142:4 147:7	speaking (6) 26:12 37:11 44:15 155:10 175:8 193:17	spinal (1) 124:25	starts (3) 53:14 120:13 123:4
slides (1) 143:15	someone's (1) 114:17	special (2) 170:5 172:6	spine (1) 196:19	state (1) 181:4
slightly (7) 8:9 13:7 28:21 43:22 44:5 179:9 229:3	somewhat (2) 82:23 192:4	specialist (8) 6:18 168:4,10 172:5,8 172:20,24 173:18	spread (1) 187:14	stated (1) 62:12
slim (1) 193:12	sorry (46) 10:7 20:16 21:10 35:8 35:8 45:25 46:5 48:24 51:2 56:12 58:6,6 59:13 60:3 65:22 75:3 79:9 80:24 91:5 92:5,6 94:4 105:12 125:20 126:12 128:25 129:25 133:8 134:18 138:6 140:13 142:2 156:5 156:19,20,22 158:25 175:10 196:24 197:23	specific (19) 15:21 16:4,5,12 17:15 24:5 28:23 39:4,5 39:23 41:4 44:10 52:14,14 111:4 115:24 143:24 152:6 178:4	spreadsheet (7) 54:6,19 55:25 57:20 149:11 153:6,7	statement (4) 143:10 151:22 204:25 226:7
slime (2) 184:8 185:14		specifically (12) 16:2 18:22 21:14 25:20 37:11 75:7 94:24 118:6 134:12	spreadsheets (1) 55:8	states (17) 1:2 14:12 15:17 17:5 19:4 61:17 85:23 148:12 161:4,8,11 172:15 174:19,23 175:12 201:17 227:14
slot (1)			squames (1) 187:2	statistical (5) 106:24 107:19 203:3 204:15,19
			Square (1) 2:17	
			squared (1) 207:7	
			SSI (11) 45:21 65:14 66:4,8,23 68:14 69:3,8 102:24 120:15,16	
			staff (3)	

statistically (1) 107:16 statistics (1) 57:3 stats (2) 125:5 223:17 status (1) 66:8 stay (1) 107:11 steer (1) 142:11 step (2) 35:13 69:11 stepping (2) 11:12,13 steps (2) 38:16,22 sterile (5) 187:19 205:24 206:7 207:11,12 sterilized (1) 187:15 stick (2) 41:9 42:19 sticker (1) 197:6 stock (1) 14:14 stop (5) 46:21 70:18 85:9 86:2 153:13 stopped (3) 120:24 148:17 153:23 stopping (1) 12:2 stops (1) 13:2 straddles (1) 25:9 Street (4) 2:12,22 6:5,15 strict (1) 207:8 strike (8) 8:19 24:8 36:24 54:18 66:11 128:6 178:16 184:13 strong (1) 141:17 structure (2) 9:16,17 structured (1) 223:17 structures (1) 172:12	struggling (3) 59:2 111:18 113:14 studies (40) 37:21 38:12 39:13,24 39:24,25 40:23 41:4 41:9,10,23,25 42:2 42:3,4 69:21 70:6 79:20 80:11 115:23 162:8 192:3,10,15 192:19 194:23,24 195:2,4,13 199:14 209:6,11 210:11,15 226:12,15,18 227:6 227:25 study (124) 5:9 22:4 23:17 24:18 24:19 25:14,23 27:25 28:13 32:9,23 33:13,22 37:22 42:24 44:25 45:8 47:2 59:19,22 62:9 62:20 63:15 70:5,5 70:8,10 89:18,23 90:2 103:17 104:2 104:11 105:5,16 106:14 110:2,14,17 116:7,12,14,24 117:2,19,22 129:20 136:12 144:6 145:23,25 146:2 147:17 159:9,9 160:14 178:6 191:24 194:5 196:12,14,16 197:6 197:9,9,24,25 198:4 198:5,22,22 199:2,4 199:19 201:4 202:3 202:23 204:6,20 205:3,7 206:10,11 208:25,25 211:17 215:8,12,14 217:21 218:5,6,18,22 219:12,17,24,25 220:3,4,20 221:15 221:16 222:2 223:2 223:4,18,19,20,24 223:25 224:6,8,11 224:12,14,14,19,22 224:23,24 225:11 228:9 229:9 studying (1) 71:12 stuff (5) 35:2 37:20 68:22 70:4 226:23 subject (5)	26:3 37:18 39:14,14 69:20 submit (5) 32:9,13,14 46:17 73:12 submitted (8) 30:6,9,25 32:11,14,16 40:9 144:6 submitting (1) 145:3 Subparagraph (1) 17:8 subpoena (1) 55:9 subscribe (2) 180:17,19 subsequently (4) 30:6 95:7 139:13 175:19 subset (1) 16:2 substance (1) 162:20 substantive (2) 162:13,14 success (1) 73:14 successful (1) 69:3 sucked (1) 27:18 sucking (1) 27:12 sufficient (1) 95:4 sufficiently (1) 108:2 suggest (4) 43:11 137:19 142:9 149:6 suggested (2) 150:13 151:15 suggesting (1) 223:21 suggestions (1) 180:9 suggests (1) 96:10 summarize (1) 86:24 summary (4) 77:2 87:18 133:16 226:10 summer (2) 25:3 148:13 Sunday (3)	6:2 230:6 231:5 superficial (4) 112:15 120:20 178:10 178:12 superiority (2) 223:19,20 supplying (1) 100:22 support (1) 112:2 suppose (4) 38:20 159:3 176:21 223:3 supposed (1) 16:22 sure (51) 24:2 26:5,6,20 28:7 29:8 31:16 32:15 33:7 38:25 44:14 57:10 61:14 64:17 79:6 81:9,10,11 86:19,20 90:20 92:23 94:7 95:24 96:8 98:4,9 107:25 109:9 113:3 117:19 117:20 118:7 124:15 144:17,23 146:11 161:10 174:15 179:20,22 184:19,21 190:17 196:5,6 198:7 199:25 220:12,25 223:17 surgeon (11) 7:25 8:3 75:8 78:8 158:18 167:23,24 169:8,18 186:7 207:5 surgeons (19) 31:4 134:22 154:10 154:14,19 168:18 169:6 170:12,22,23 170:25 173:14,17 174:12,21,22 175:5 185:4 208:10 surgeries (11) 29:11 62:10 66:4 82:11 169:11 181:23 182:3 190:6 190:10 198:14,19 surgery (31) 9:23 11:7 58:22 59:21 59:24 60:3 65:16 116:9 169:20 174:3 177:3,15,25 182:17 184:24 188:13	189:21 192:23 195:16 198:17 213:8 214:21 215:2 215:13 217:13,16 217:16,19,23 226:24 227:7 surgical (22) 12:6,8,12 13:13 45:21 56:20 65:16 67:5 68:5 71:4 97:17 111:21 168:2,3 170:13 192:16 206:20 209:14 210:3,16 211:6 214:10 surprised (1) 31:11 surrounding (1) 191:17 surveillance (22) 45:3 46:14,15,15,18 51:25 56:21 57:2 59:20 60:13,19 61:5 62:17 63:21,24 65:14,17 67:5,15 69:10,14,18 susceptible (6) 114:9 184:5 185:22 193:18 210:4,18 suspect (4) 59:18 119:2 138:19 141:8 suspicious (1) 211:11 sustained (4) 67:25 202:11,13,25 sustains (1) 188:6 switch (24) 21:8 78:6,6 82:10 83:20 84:13 85:4 86:15 88:10,12,12 88:13,16 94:4,5 96:19 97:25,25 99:4 101:14 102:3,4 112:18 113:20 switched (21) 78:3,7,8 82:12 83:5 83:11 85:8 88:7 89:16 93:8,11,16 94:3,7,14 97:21 101:9 102:7 108:3 116:12 118:11 switching (5) 83:15 94:11,13 112:2 119:21
---	---	--	---	---

sworn (1) 7:10	110:25 121:25 202:5	141:12	27:13 28:15 33:9 34:13 72:6 87:24,24	71:11 72:2,14,18,20 74:11 75:18,18,19
sympathy (1) 18:6	talked (7) 34:9 35:3 145:22	ten (6) 30:21 73:5 95:8 122:8 152:17 157:11	88:3 92:17 94:18 109:6,8,10,14 111:8	77:7 78:8,21 81:16 81:22 83:13 85:17
system (11) 61:3 67:15 78:11 79:5 109:2 120:19 150:3 150:4 152:25 154:4 172:15	160:2 176:23 177:6 178:15	tend (3) 31:14 147:18 168:19	116:4 120:25 121:18,21 142:21 152:12 175:16 178:25 201:10 211:18,22	88:25 90:5,7,9 92:2 92:23 93:18 94:7 95:8 97:4 98:6,18 101:18,25 104:3 106:21 108:15,15 111:18,19 112:19 113:5,9,14 114:2,11 114:22 116:2,24,25 117:13,20,22 118:24 119:15,24 120:10 121:4,5,14 123:16,17 124:3,6 124:13 126:8,13,22 127:2,2 128:5,16,17 128:21 129:3,19 134:8,8 135:11 136:3,14 137:3,9 139:19 140:15 141:3,6,21 143:8 144:7,8 145:13 147:20 148:2,5 150:13,25 152:18 154:22,25 157:6,11 157:16,18,19,20 158:15,21,23 159:3 162:18 164:18 166:10,14 169:25 170:24 172:2,5,19 173:20 175:11,18 175:21 176:2,21 177:24 179:10 180:25 182:25 184:11,20 186:25 187:7 188:4,22 190:11 192:13,18 195:17 199:22 201:3,5,9,13 203:9 205:14 208:2,3,5,9 209:3,10 213:9 215:18 216:19,22 217:8,8 218:3,6,11 222:3,7 223:20 224:4,13,15,15 226:7,9,10 229:6,11 229:12
systems (4) 52:11 153:17 154:2 154:17	talking (14) 27:5 43:8 55:22 86:15 107:5 109:20 116:10 133:7 157:16,17 175:23 186:18 191:13 193:11	term (3) 33:15 177:24 185:17	theater-based (1) 25:18	
systems (4) 52:11 153:17 154:2 154:17	talks (2) 174:23 195:4	terminology (1) 85:17	theaters (5) 9:21 35:22 50:3 78:14 78:15	
T	tape (6) 93:4 95:11,13,19 183:6,12	terms (16) 45:7 109:2 110:4 111:19 120:2,2 129:8 132:6 158:7 165:12 193:5 212:24 217:8 221:18 226:9 227:12	theoretically (1) 177:5	
T (2) 148:24 232:3	target (1) 145:8	terrible (2) 182:21,21	thereabouts (1) 81:13	
tab (14) 19:25 146:6 155:13 155:24,25 195:3 196:22 197:5,7 200:3 203:11 211:25 212:2 220:5	targeted (1) 189:17	territory (1) 61:7	thereof (1) 230:7	
tabbed (2) 17:11 20:18	task (1) 129:12	test (4) 31:10 92:24 107:19 107:21	thing (18) 8:10 13:6,7 16:19 35:20,25 36:17 73:22 74:16 107:10 108:16 111:22 120:13 132:19 142:22 146:24 158:3 215:5	
table (10) 48:11 55:19 57:21 77:2 197:20 206:19 206:23 207:2,5 209:8	team (17) 45:3 46:15 51:24 52:14 56:21 57:2 60:13 62:17 63:21 65:17 67:5,6 68:13 69:18 136:15 158:12 159:2	testified (5) 7:11 138:25 208:16 209:21 226:23	things (33) 17:25 22:9 23:22 24:20,22 29:18 32:13 35:16,23 42:6 42:18 67:23 74:18 76:24 78:7 86:8 111:12 119:16 120:4 138:19 145:5 151:16,19 152:24 161:25 181:7 186:17,18 187:9 204:22 207:3 220:18 222:5	
tablet (1) 94:8	techs (1) 29:19	testifying (1) 130:19	think (226) 8:4,6 9:18 11:2 13:7 13:14,16 14:3,13,19 15:14 18:2,12 21:7 22:19,19 23:9 24:16 25:9,12,16 26:9,11 27:2 28:10,22 29:17 30:5,22 31:8 32:6 33:15 34:5,25,25 37:23 38:18 39:4,4 43:9,14 45:4,15 46:13 48:9 49:22 53:13 55:5 58:17 61:16,20,23 62:5 67:23 68:21 69:17	
tactics (2) 77:3,6	teeters (1) 205:14	testimony (10) 45:12 49:9 62:11,23 103:12 204:8 227:5 230:6 231:4,7		
take (35) 14:14 19:12 34:6 36:3 38:22 42:20 52:17 64:11 84:14 86:22 98:4 100:20 104:7 114:14 117:5 130:14 131:14,16 131:17 132:3 135:13 144:25,25 149:5 163:6,15,16 169:9 171:7,16 180:9 187:23,25 188:10 223:4	teicoplanin (11) 83:17,25 84:14,17 89:17 90:3,14 91:10 98:2 101:10 102:9	testing (1) 108:20		
taken (13) 1:24 6:4 49:7 63:7 72:18 95:17 122:10 160:22 183:10 196:3 201:5 230:6 231:5	tell (18) 19:24 20:23 21:16 30:21 55:6,25 58:13 59:8 71:6 96:5 103:19 121:9 127:14 155:13 166:19 177:10 199:2 223:9	tests (2) 198:7,8		
takes (1) 169:7	telling (1) 125:21	Texas (1) 3:7		
talk (6) 26:18,24 84:19	tells (1) 208:19	text (5) 46:3 133:13 147:5 175:18 176:3		
	temperature (2) 40:21 225:15	thank (22) 7:16 45:20 46:4 49:3 50:14 65:24 83:3 84:8,11 100:21 142:10 143:16 145:16 155:8 156:15 160:18 166:13 213:20 229:17,18,19,21		
	temporal (1) 193:7	Thanks (1) 148:25		
	tempted (1)	theater (30) 12:5 25:11 26:8 27:7		
				6:19 47:20 189:24 226:2 thought (13) 13:10 36:16 88:16 138:8,10 142:13 143:17 176:24

197:23 198:3 215:19 227:22 228:22 thousand (1) 185:14 THR/TKR (2) 66:5 105:24 three (21) 9:24,25 33:21 45:4 47:18 50:9,22 55:2 86:13 97:13 143:15 151:16 155:6,16,19 180:25 181:2,3 192:13 221:21 222:16 thrombo-prophylac... 179:18 211:16 thromboprophylaxi... 11:24 12:2 13:5 92:9 93:7 98:12,12,15 99:16 102:16 103:6 103:10 105:7 106:10 108:12 110:17,21 212:22 thrust (1) 13:19 tie (1) 41:4 till (2) 47:25 102:20 time (104) 6:16 8:15,24 10:24 12:19 13:3,4,15,25 17:24,24 18:12,22 24:23,24 27:16 29:13 31:15 41:3 45:4,9 46:19,24 51:14 55:3 59:19 64:16 66:21 69:14 72:16 78:3,10 82:22 83:14,18 89:25 91:17 96:10 99:2 100:3 101:12 102:14,14 103:17 105:15 108:2,25 113:23 114:7,8 115:11 116:12 117:5 118:16,22 119:18,23 120:6,24 121:5 124:6 128:19 133:2 139:9,20 140:24 144:18 147:15 148:9,11,13 155:4,5,9,17,21 163:6 164:22 169:7 183:2 187:15,15	189:7 193:8,10 196:3 198:17 201:11,23 203:3,22 205:7 206:11 207:9 210:20,25 213:25 214:2 219:23 221:20 224:7,18 226:21 229:11 timeframe (5) 29:10 80:15 106:13 108:9 119:9 timeline (15) 71:16,25 78:5 79:7,8 79:13 81:4,24 82:2 112:19 115:15 117:11 120:12 121:9 145:13 times (7) 166:18 185:15 209:22 209:22 219:15 222:16 228:5 timescale (3) 68:9 215:4 227:20 timing (1) 64:10 timings (1) 25:11 tinzaparin (9) 92:21 93:9,14,16 94:3 97:22 104:25 106:5 106:17 tissue (1) 189:15 title (9) 7:19 76:11,13 172:3 199:5,7,9 212:17,19 titled (3) 5:6 135:17 199:16 titles (1) 11:6 TKH (1) 121:19 today (17) 29:6 49:9 82:22 89:24 134:5 149:10 152:18 161:19,21 178:7,7 191:16 209:8 211:14 216:3 218:15 227:18 told (3) 34:23,25 35:2 tomorrow (1) 133:17 top (12) 9:7 23:11 36:9 39:21 46:2 117:18 123:18	124:22 130:5 144:13 146:18 197:20 topic (3) 26:18 142:17 195:7 total (6) 9:18 66:4 196:17,17 198:15,15 touch (2) 201:7 214:5 touched (2) 40:11,12 tour (3) 148:12 174:22 201:17 town (1) 201:18 track (4) 58:10 97:7 120:23 141:3 traditional (1) 22:10 train (5) 169:7 172:24 173:3 173:15,18 trainee (2) 141:22 172:16 trainees (7) 11:11 29:25 32:12 173:6,7,7 177:7 training (19) 8:25 10:25 11:8 164:16 167:2,14,15 167:19,21,23,24 168:4,7,11 173:4,5 173:12,19 177:7 transcribed (1) 231:6 transcript (3) 147:2 231:5,7 transcription (1) 230:7 transfusion (8) 118:5 148:25 149:15 149:18,22 151:2,6 151:20 transit (1) 186:22 transition (7) 25:4 47:20 49:25 50:6 91:25 92:3 97:9 transitioned (2) 47:9,13 transmission (1) 186:23 transportation (1) 185:21	trauma (24) 9:21,22 60:23 61:2,10 61:15,19 62:6,21 63:13 76:3 159:18 159:19 168:4,7,11 169:3,9,15,19 171:10,12 173:7 174:3 travel (1) 135:7 traveling (1) 174:20 treat (4) 38:21 142:12 178:12 185:8 treated (1) 188:9 treatment (2) 37:9 94:8 trial (36) 14:14 16:22,23 18:16 18:23,23 34:18,24 35:14,15 36:3,8,9 36:13,14,16,19 37:15 38:13 39:2 41:14,16 65:8 77:25 112:6,10 158:4,5,8 158:10,13 159:8,11 162:2 218:4 225:2 trialing (1) 153:25 trials (7) 35:21 36:11,12 37:2 39:8 159:6 161:25 tricky (1) 58:13 tried (1) 119:16 trouble (2) 95:2 201:6 true (7) 32:6,6 204:18,25 208:9 230:7 231:7 trust (13) 9:13,14,15,18 29:14 66:3,7,22 67:9 68:14 85:24 213:24 224:3 trusts (4) 9:11 10:23 67:15 95:8 truth (2) 79:6 127:9 try (9) 48:22 62:21 67:25 143:7 163:14 189:15,22 198:11	227:15 trying (19) 26:4 35:12 38:10,15 48:23 78:21,24 80:21,22 92:24 97:7 114:16 119:12,14 145:13 159:10 176:21 181:10 223:9 TSG (2) 6:18,20 turn (23) 19:18 22:25 23:20 55:5 70:23 72:4,9 75:23 76:9 96:17 111:7 126:11 127:18 129:21 139:23 142:2 144:4 144:12 146:17 150:17 153:7 200:3 211:25 turns (1) 40:18 TV (3) 27:15 28:16,21 twice (2) 141:9,23 two (45) 8:23 10:19 14:18 15:20 17:18 23:22 24:20 25:5,15,19 29:25 31:21,22 54:14,21 66:2 69:3 70:2 86:8 97:24 98:11 99:8 105:19 107:4 111:4 126:7 129:20 136:13 143:15 148:23 164:9 167:13,22 168:5 176:2 188:17 199:23 200:19 204:22 205:17 213:23 214:20 223:10,13 228:7 Tyneside (2) 10:20 54:25 type (6) 42:13 58:20 68:3 194:7,7 201:25 types (3) 25:6 169:20 212:15 typical (2) 36:19,21 <hr/> U <hr/> U.K (16)
---	---	--	---	---

6:15 7:15,20 8:9 36:22 63:22 85:10 141:15 160:7,9,10 169:7 176:8 225:17 226:5 227:12 U.S. (20) 6:24 7:22 15:10 16:24 18:11 19:7 31:16 36:23 64:25 65:4 77:18 85:19 160:7,9 168:25 169:4,8 176:8 201:3 207:4 U.S.A. (1) 227:16 ultimately (4) 35:18 60:22 122:23 147:20 ultra-clean (1) 4:25 uncertain (1) 53:19 unclear (1) 82:23 uncommon (1) 190:9 undergoing (1) 153:16 underneath (1) 206:19 understand (26) 7:18 19:6 20:12 31:17 35:12 41:24 49:11 56:9 57:15 73:4 79:25 87:6,9 91:22 100:7 101:24 120:17 136:25 138:13,13 155:16 161:10 162:24 176:14 194:25 198:10 Understandable (1) 172:23 understanding (10) 129:9,15 133:18,21 166:16 178:21 182:15 187:7 195:25 222:9 understood (3) 41:8 124:12 163:4 underway (3) 113:5 119:3 158:8 underweight (1) 193:23 underwent (1) 105:24 unfortunately (6)	31:14 44:5 57:13 59:2 165:4 223:24 unfunded (1) 34:17 unhealthy (1) 150:5 unidirectional (5) 191:25 206:14 216:3 216:6,20 unit (2) 207:16,19 United (17) 1:2,16 2:12,17 6:6 14:12 15:17 19:4 85:23 161:4,8,11 172:15 174:19,22 175:12 227:14 units (3) 207:25 208:17,20 universal (1) 171:16 university (3) 167:12 172:17 180:21 unnecessary (1) 18:13 unpaginated (1) 20:8 unpublished (1) 41:25 unrealistically (1) 67:14 unrelated (1) 162:3 unreliable (3) 64:7 149:2,16 unsure (1) 191:10 untimely (1) 14:20 unusual (3) 37:5 73:19 147:8 update (5) 12:7,11,23 13:13 164:23 updated (2) 82:4 133:16 updates (1) 201:5 updating (1) 12:24 upfront (1) 215:25 uploading (1) 67:6 use (26) 14:16 15:16 27:23	47:23 49:5,13 50:22 62:8 72:11 76:10 77:8 82:11 85:11,12 85:21 97:13 100:12 139:25 153:11,15 154:4,14,19 189:12 225:17 226:4 useful (4) 39:21 150:24 153:2,3 usual (1) 37:10 <hr/> V <hr/> valid (1) 37:14 value (5) 107:18 120:22 150:11 203:6,8 variety (4) 78:7 112:11 119:19 152:22 various (4) 22:9 52:8 189:12 212:15 vascularity (1) 185:12 venous (3) 11:24 13:5 92:9 ventilation (1) 4:25 vents (1) 122:6 verbal (1) 163:14 verbatim (1) 231:7 verify (3) 81:12 141:13 144:22 versa (1) 109:11 version (16) 20:8 40:16 79:19 126:22 127:12 164:13 176:11 213:7,11,15,16 220:10,13,15,17,23 versions (2) 127:11 221:2 versus (3) 103:21 159:23 204:23 viable (1) 207:22 vice (1) 109:11 video (2) 6:17 26:5	videographer (13) 3:17 6:9 95:13,19 122:8,12 155:4,6 160:20,24 183:6,12 229:22 videos (3) 33:5,7 158:16 VIDEOTAPED (2) 1:11 6:3 Vienna (2) 127:4 129:19 view (2) 125:24 182:10 viewed (1) 32:25 viewpoint (1) 162:14 vigorous (1) 40:2 virtually (1) 49:11 vitae (1) 164:7 volume (21) 17:16,21 19:12,19,20 19:21 20:3,6 52:17 54:19 64:12 122:13 126:13 128:24 129:2 132:18 154:22,25 155:2,3 155:12 volumes (2) 13:20,21 voted (1) 175:19 vouch (1) 144:24 vv (2) 202:10,10 <hr/> W <hr/> W-I-M (1) 127:20 waive (1) 56:11 waives (1) 65:6 wall (1) 71:24 Wansbeck (15) 10:6,8,9,16 29:2,3 51:21 54:25 58:3,18 78:4,11 113:23 120:17 121:6 want (58) 14:4 15:11 16:19	21:14 24:5 31:16 38:3 42:23 53:22 56:10 64:10 71:15 73:7 80:8 86:25 87:13 92:24 98:7 100:2,12,16,20,25 119:6 121:24 122:13 124:21 128:25 129:22 130:5,7 132:18 133:25 135:16 142:3 143:14,21 146:8 155:12 157:3 162:21 163:6,19 166:21 170:17 190:17,19,22 191:3 195:22 198:12 200:3 202:2 209:3,3 210:6 227:15,17 wanted (5) 134:6 151:10 160:15 162:8 228:19 wanting (1) 224:6 wants (1) 140:4 ward (1) 109:10 warm (5) 115:17 116:4 217:2 217:15,19 warmed (4) 47:6 116:8 117:21 118:2 warming (61) 1:5 4:25 6:11 21:18 23:5,24 25:6,11 27:7,8,23 31:21 36:5 37:16 47:9,10 49:25,25 73:23 74:17 118:7 123:11 123:13 125:11,20 125:20 129:6 132:8 135:6 142:18,19 154:3,4 157:21 158:6,6 159:23,23 175:17,24 199:17 202:20 204:7 206:12 209:7,7,10 211:7 216:19 217:12 218:2 219:16 223:5,6 225:14,16,17,23 226:9 228:4,5 wasn't (27) 28:19 31:12 32:15
--	--	---	--	--

28:19 31:12 32:15 34:9,19,23,25 54:2 78:14,15 86:21 89:25 98:24 102:22 106:21 119:21 125:21 127:11 133:24 135:3 136:17 151:14 173:20 201:22 205:16 215:22 218:21 Watchdog (2) 72:19 73:13 Watts (1) 140:7 way (26) 18:18 19:5 26:23 40:25 41:5,16 42:5 42:21 43:18 44:7 48:21 52:6 58:10 61:14,16,18 62:21 79:17 109:9 114:21 141:3 149:17 157:22 170:7 218:22 231:10 ways (2) 30:19 85:25 wazoo (1) 71:21 we're (1) 190:13 we've (2) 90:9 159:15 wear (3) 59:3 109:6,8 website (1) 165:22 week (4) 32:22 123:19 127:10 200:19 weekend (1) 28:15 weeks (6) 13:23 133:2 164:9 204:14,17 220:18 weight (7) 128:14 211:18 212:22 213:2 214:20,25 215:8 went (16) 22:14 26:23 27:17 46:14 69:14 88:6 92:15 93:14 97:8 106:17 135:11 148:9 167:12 168:9 168:13 169:23	weren't (5) 39:24 95:7 99:18 116:8 140:23 WG (1) 54:25 WGH (1) 121:18 Whereabouts (1) 77:11 Whilst (1) 123:8 whimsical (1) 151:22 wide (2) 61:25 173:17 wider (1) 165:25 wife (1) 11:12 willing (1) 224:5 Wim (2) 127:20,24 winding (1) 155:15 window (1) 108:10 wish (5) 19:9 24:4 37:24 43:14 200:25 withdraw (1) 92:5 withdrawn (1) 38:21 withstand (1) 218:14 witness (13) 2:13,18 15:23 39:16 42:15 53:19 72:11 80:20 81:19 100:22 139:5,19 231:5 witness's (2) 49:8 80:11 witnesses (3) 16:11 17:21 26:12 won (1) 74:16 wondering (1) 138:13 Wood (1) 218:11 word (2) 11:25 98:4 wording (1) 161:10 words (10)	14:22 15:2 28:5 59:21 66:18 97:25 110:20 140:23 178:16 228:2 wore (1) 109:3 work (19) 7:14 30:10 39:14 91:17 120:9 129:7 140:14 142:12 149:5,20 151:9 166:3 175:23 181:8 185:15 189:22 205:18,19 208:3 worked (1) 146:22 working (5) 68:3 148:15 172:8 223:14,15 works (2) 52:6 141:3 world (2) 176:7 178:14 worse (1) 122:4 worsen (1) 199:17 worth (2) 151:12,14 wouldn't (16) 29:17 32:12 37:8 53:16 61:18 62:5 92:14 100:9 111:11 147:13 152:4 165:17 173:13 187:17 206:3 211:10 wound (16) 5:6 94:22,24 112:13 113:5 177:22,24 178:10,13 183:23 184:2 189:14 193:5 193:7 212:20 214:18 write (3) 147:9,11 202:8 writer (1) 124:2 writing (3) 101:4 128:4 157:5 written (15) 15:4 48:5 60:20 64:20 67:13 75:12 86:8 89:15 100:3 109:23 113:19 128:17 129:11 180:3	216:23 wrong (4) 43:21,22 75:22 78:13 wrote (6) 70:2 82:14,15 124:8 152:17 175:18 <hr/> X <hr/> X (1) 4:2 xarelto (7) 211:15,19 214:9,19 214:24 215:9,16 Xs (1) 221:22 <hr/> Y <hr/> year (19) 8:13,25 10:13 12:16 13:6 25:12 46:17 64:6 92:2 141:15 148:11 153:14,19 175:21,21 177:4,5 180:24 188:15 years (28) 8:4,11,12,13,23 12:24 13:3,12 39:7 47:18 73:18 79:15 82:2 115:9 117:9 120:11 167:22,24 168:5,7 168:19 181:3 187:23 188:17 189:3 192:13 199:10 225:4 yellow (3) 112:24 117:15,18 yesterday (9) 43:19 64:15 72:16 75:11,22 147:2 182:12 201:22 213:6 York (1) 6:19 younger (1) 80:6 <hr/> Z <hr/> Zealand (6) 9:2,2 168:9,12,13 171:17 Zimmerman (6) 3:13 7:2,2 48:10 137:8 146:6 <hr/> 0 <hr/> 0 (1)	107:18 0.102 (1) 107:18 0.6 (1) 202:9 0.66 (2) 88:5,6 0005490 (1) 55:7 0018360 (1) 156:8 <hr/> 1 <hr/> 1 (48) 4:17 13:21,21 14:7,11 15:12 19:12,12,14 19:19,20,21 20:3 21:2 95:13 96:3,24 104:17,20 105:2 106:14 107:17,23 108:9,9 113:15 130:13,14 131:13 131:14,18 150:4 154:22,23,25 155:2 155:3,12 169:6 194:7 196:22 197:5 197:7,20 204:16 208:12 230:5 231:5 1,000 (2) 151:12 223:11 1,700 (2) 14:18 16:25 1.0 (3) 220:10,17,23 1.3 (1) 202:10 1.5 (1) 36:17 1.52 (2) 88:5,6 1.6 (1) 202:10 10 (8) 5:4 54:18 149:4 203:14,19 208:5,16 209:20 1047 (3) 58:2,7,16 1050 (1) 63:9 1051 (4) 57:12,17 59:7,10 1060 (3) 61:9,12,13 1081 (8) 52:18,22 53:6 54:20
---	---	---	---	---

55:22 56:15 63:9,16 1082 (2) 55:5,11 1083 (2) 55:5,11 11 (7) 5:5 9:18 191:14,18 212:5,8,11 115 (1) 5:3 115951 (1) 1:25 116 (1) 200:16 117 (1) 4:22 117,000 (1) 224:17 118 (3) 5:4 203:11,16 12 (6) 5:6 6:16 9:19 90:25 213:21,22 12-month (1) 69:4 12,000 (1) 215:12 12:30 (1) 6:7 13 (6) 5:8 8:4 200:3 201:24 220:6,7 130 (1) 166:14 14 (6) 17:12 18:3,6 19:10 190:11 203:11 14-2666 (1) 1:7 140 (1) 166:14 1479 (4) 129:21,22 130:2,6 1480 (1) 129:22 1492 (2) 132:20 133:6 1494 (1) 132:20 1496 (3) 133:9 134:11,20 1498 (1) 133:6 15 (6) 9:2 59:4 189:3 190:11 219:9 225:10	15-2666 (1) 6:12 1500 (4) 133:6 135:16,19 136:19 1501 (1) 139:23 1505 (5) 132:20,21 133:6 135:16 142:2 1519 (2) 148:20,21 1521 (1) 150:17 1522 (1) 148:20 1529 (2) 144:12,13 1532 (1) 146:17 1535 (1) 144:13 154 (1) 4:8 1543 (2) 4:21 100:22 1556 (1) 214:12 157 (1) 4:23 1584 (3) 122:15,18,20 1585 (1) 124:8 1589 (1) 122:18 15th (2) 59:25 60:4 16 (1) 23:12 1601 (1) 124:18 1602 (1) 124:22 1607 (1) 124:18 1609 (3) 221:7,8,22 1616 (1) 3:12 172 (1) 225:10 18 (5) 4:17 10:13 167:9,11 220:6 189 (1)	4:24 19 (1) 4:18 192 (1) 5:2 195 (1) 5:4 1992 (1) 167:20 1994 (2) 8:16 168:2 1996 (3) 168:3 218:6,7 1AE (1) 2:12 1st (14) 45:24 46:11 47:5 50:3 50:4,11,12 53:14 63:17,19 88:22 89:4 91:8 106:5 <hr/> 2 <hr/> 2 (17) 4:18 20:6,7 36:17 64:12 77:9 95:19 96:23 121:18 126:13 129:2 131:16 164:25 169:6 183:6 194:7 204:16 2,700 (1) 166:18 2.4 (1) 207:7 2.5 (5) 47:18 104:18 106:17 107:17,24 2.5-year (3) 45:24 46:21,24 2:28 (2) 95:15,16 2:37 (2) 95:18,21 20 (6) 51:12,15 90:17 144:13 190:23 227:21 200 (1) 31:4 2001 (2) 116:10 117:23 2002 (4) 53:17 168:15,16 171:22 2003 (3) 8:6 11:3 172:2	2004 (3) 8:6,6 11:2 2006 (1) 64:5 2007 (8) 53:14 63:17 68:9 69:12 83:6,12 85:13 86:3 2007/2008 (1) 45:15 2008 (18) 45:24 46:12 47:5 48:19 50:17,18 63:19 68:8,15 69:15 84:15 88:22,24 89:8 97:8 99:3 113:6 121:13 2008/2009 (1) 66:2 2008/early (1) 119:9 2009 (35) 26:9,12 27:6 29:10,13 34:18 84:2,15,17 88:18,24 89:8,8 91:8 93:18,21 96:2 96:24 98:17,17 99:4 99:5,21 102:7,8,20 102:20 105:23 106:6 112:22 113:15 118:25 119:9 158:4 224:9 2010 (39) 25:3,13 34:14 48:8,20 50:3,4,7,11,18 59:4 59:15,25,25 60:4 78:9,9 92:4 93:18 93:21 96:2,24 97:9 97:10,11 99:5 105:23 110:19 114:11,21 117:13 117:25 118:15,19 144:9,13 145:13 191:14,18 2011 (7) 24:16,18 72:19 136:6 199:4,6 200:22 2012 (10) 23:12 72:6 136:6 174:20 200:20 201:13,14,16,24 213:8 2013 (12) 12:13 13:14 22:2,4 23:9,11,13,18 121:18 127:5	175:11 176:12 2014 (2) 13:15 170:15 2016 (13) 1:24 6:2,4,16 49:7 164:10 216:24 220:10,24 221:17 230:6 231:6,24 204 (1) 5:5 205 (1) 5:6 21 (1) 155:7 211 (1) 5:8 214 (2) 165:10,13 219 (1) 4:9 21st (1) 164:10 22 (2) 124:9 225:10 23 (1) 8:17 232 (2) 230:5 231:5 25 (1) 195:14 28 (2) 88:18 96:24 2nd (1) 200:22 <hr/> 3 <hr/> 3 (17) 4:19 21:2 52:17,19 54:19,19 84:18 90:8 102:10 121:11 122:8 129:24 130:13 131:13,17 156:13 183:12 3-point (1) 218:24 3.5 (1) 66:6 3.8 (8) 218:24 219:15,20 227:25 228:4,5 229:5,8 3.9 (2) 229:5,8 3/2008 (1) 121:10 3:11 (3)
---	--	---	--	---

122:9,11,12 30 (2) 105:25 215:5 300 (2) 20:4 31:4 371 (4) 156:2,14,16,17 387 (1) 20:5 3M (26) 2:23 6:23 160:5,5,5 160:14 161:17,23 162:2,12 176:14 201:21,23,25 221:20,25 222:9,17 222:20 223:2 224:10,15,21,24,25 225:4 3rd (3) 59:14,15,25 <hr/> 4 <hr/> 4 (22) 4:22 6:2,15 13:21,21 14:7,12 15:12 21:3 102:9 122:13,16 129:25 146:6 175:23 195:15,23 196:8 221:3,3 230:6 231:5 4.5 (2) 84:16 85:6 4:06 (1) 160:20 4:07 (1) 160:21 4:17 (2) 160:23,24 4:44 (2) 183:8,9 4:48 (1) 183:14 4:49 (1) 183:11 40 (1) 227:22 400 (3) 84:18 202:5,6 42 (1) 219:10 421 (2) 70:23 71:2 425 (2) 75:2,4 427 (1) 75:7	431 (2) 2:22 75:4 436 (2) 72:4,5 4409 (1) 3:7 446 (1) 72:9 451 (1) 72:5 453 (2) 75:23,24 454 (2) 76:9,16 457 (2) 72:5 75:24 460 (1) 58:10 4602 (10) 57:16,23 58:2,12,14 58:17,17 59:7,11,24 487 (4) 64:12 65:23,24,24 490 (1) 64:12 4th (2) 1:24 6:4 <hr/> 5 <hr/> 5 (8) 4:20 81:6,7 150:5 155:25 195:15,17 197:19 5,000 (1) 28:3 5.5 (1) 202:10 5.7 (1) 66:6 5:53 (2) 229:23,24 50 (3) 4:19 190:22 191:8 505 (9) 19:18,21 21:11,12,15 126:24 128:21,22 128:24 510 (2) 21:15 126:24 52 (1) 107:7 521 (7) 96:17 104:8,13 105:20,22 107:7,11 522 (1) 96:21	523 (1) 104:15 525 (5) 96:17 104:8,13 105:20 107:11 527 (1) 86:22 531 (1) 86:22 533 (3) 22:25 23:13 45:17 534 (1) 23:11 538 (1) 22:25 540 (4) 23:20 43:6 84:7 92:25 543 (8) 43:9 45:18,20 49:18 84:10 101:18,20,25 546 (6) 48:4,11 100:7,23 109:25 110:9 547 (2) 23:20 92:25 548 (1) 68:12 5491 (1) 55:7 55404 (1) 3:13 55415 (1) 2:22 5GS (1) 2:17 5th (2) 220:24 221:17 <hr/> 6 <hr/> 6 (4) 4:21 101:5,6 219:3 60 (3) 59:23 106:2 189:18 67 (4) 11:10 173:5,7,12 6LB (1) 6:6 <hr/> 7 <hr/> 7 (12) 4:6,7,21,23 6:5,15 52:20 163:24 164:3 164:6 195:3 231:24 70s (1) 159:14 71 (2)	65:19,22 718 (4) 126:11,14,15,18 739 (2) 126:11,15 74 (1) 80:17 741 (2) 127:18,19 747 (1) 6:18 754 (1) 127:18 76 (1) 58:19 77006 (1) 3:7 78 (1) 4:20 788 (9) 52:17,22 53:6,15 54:20 55:22 56:15 63:9,16 <hr/> 8 <hr/> 8 (8) 4:24 197:5,15 200:20 211:25 212:2 218:23 225:15 80s (1) 159:14 84 (3) 5:5 212:4,7 85 (1) 2:12 <hr/> 9 <hr/> 9 (4) 5:2 200:8,9 220:10 90 (1) 124:15 97 (1) 4:21 99 (2) 5:5 212:7
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EXHIBIT DX10

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN THE MATTER OF)

IN RE BAIR HUGGER FORCED AIR)
WARMING)
PRODUCTS LIABILITY LITIGATION)

Plaintiff,)

v.)

3M COMPANY AND ARIZANT)
HEALTHCARE INC.)

Defendant.)

)PRETRIAL ORDER NO: 7
)Protective Order
)MDL No. 15-2666
) (JNE/FLN)

DEPOSITION OF PAUL MCGOVERN

VOLUME I

Wednesday, January 4, 2017

AT: FAEGER BAKER DANIELS

Taken at:

7 Pilgrim Street
London EC4V 6LB
United Kingdom

Court Reporter: Louise Pepper

Videographer: Simon Addinsell

Job No: 117119

Page 18

DR. PAUL MCGOVERN

don't know if the hospital or the trust made a whole scale or a wholesale switch to a different device or different technology. I don't know.

Q. And when you left there, was Bair Hugger still being used for arthroplasties?

(Reporter clarification.)

A. I don't remember.

Q. Okay. So, let's go back to 2009 when you started at Wansbeck. Was that the first time you would have had any contact with Mr. Mike Reed?

A. Yes. Err ... no. Any contact whatsoever would probably have been in 2008 because he is -- or was -- fairly senior in the training of -- involved in the training of orthopedic surgeons in the northern deanery. So it is likely I would have received e-mails from him prior to 2009, probably in 2008. They would have been not to me personally; they would have been group e-mails. I don't remember the content of them, but it is likely I would have had received communication from him before then, but the first time that I started working with him was in 2009.

(Reporter clarification.)

Q. What month in 2009 did you start at Wansbeck?

A. August.

Q. Using that as kind of a benchmark time frame, when

Page 19

DR. PAUL MCGOVERN

you started at Wansbeck in August 2009, had you had any involvement in any activity or attending any seminar, reading any material, anything that would have raised any questions about the use of forced-air warming of Bair Hugger in orthopedic surgery?

A. I don't remember.

Q. Now, certainly subsequent to the time you started at Wansbeck, something got you involved in, and interested in, forced-air warming?

A. Yes.

Q. What was -- do you recall what it was that first attracted your interest?

A. As a training surgeon, there is -- one is encouraged to undertake audit activity and research activity. And so it's common practice for a surgical doctor to speak to their boss, their consultant, or someone senior to them, to ask if any research is ongoing in the department. And one of Mike Reed's research interests is infection in the operative or the perioperative period. And in fact, it's something that is taken very seriously in all hospitals, in all orthopedic departments, but Wansbeck -- there was a culture in the department of being very vigilant for possible sources of infection to -- with a view to reducing overall infection rate.

Page 20

DR. PAUL MCGOVERN

And so I was introduced to the research in question by Mike Reed, following an approach from myself to get involved with some research that was ongoing in the department.

Q. When you started in August of 2009 at Wansbeck, were you aware of any concerns that the NHS had expressed about the rate of infections in the orthopedics department at the -- in the Northumbria Trust hospitals?

A. I was not there that the NHS had expressed any concerns.

Q. And as you sit here today, you never heard that there had been concerns expressed about how high the rates of infection had been?

A. So, you say the NHS. What I took to mean by that was the higher body of the NHS. I wasn't aware if they had particularly expressed concerns. However, I was aware that there were concerns within the department that the infection rate at that trust was higher than would have been considered ideal, and there were efforts to bring it down.

Q. And when you started, were -- had all those efforts to bring it down already been undertaken, or were there still some efforts that were ongoing or yet to be implemented?

MR. SACCHET: Object to form.

Page 21

DR. PAUL MCGOVERN

(Reporter clarification.)

MR. C. GORDON: That's actually a good objection. I'll rephrase the question.

BY MR. C. GORDON:

Q. When you started in August 2009, are you aware of steps that had already been taken prior to August 2009 to reduce the infection rates at those hospitals, the Northampton Trust hospitals?

A. I was not aware of steps at the time.

Q. Okay. Subsequent to your starting there in August 2009, were you aware of any steps that were taken or procedures that were implemented, practices that were implemented, to attempt to reduce the infection rate?

A. There's a constant and ongoing effort, in any responsibly-run surgical department, to reduce infection rates, particularly in orthopedics. And so it's not a question, to my recollection, that there was a period where there weren't steps to reduce infection rates, and subsequent change. There are always efforts to reduce infection in orthopedics departments. So I don't remember a specific time when practice was -- where one could draw a line in the sand. I don't remember a specific time when that was. My recollection is of a department that was always trying to reduce infection rates.

6 (Pages 18 to 21)

Page 118

DR. PAUL MCGOVERN

period of time, September 2008 through September 2010; is that right?

A. Mm-hm.

Q. And also 1290 joint replacement cases?

A. Yes.

Q. But the data are presented differently in this figure 7; right?

A. Yes.

Q. Instead of an average infection rate across the entire time period, it's a moving average of infection rate plotted on the left-hand axis; right?

A. Yes.

Q. And in the version of figure 7 that appears on page 2218, in September 2008 the infection rate is about 3 percent. It dips down over the next several months to somewhere around 2 percent, but then sometime after March of 2009 it starts climbing up, and by sometime in between September 2009 and March of 2010, it's up to about 4 percent; is that right?

A. That's what the graph shows, yes.

Q. And if you look at the little dots that are on top, those represent the actual incidents of infection plotted on a time axis; right?

A. Yes.

Page 119

DR. PAUL MCGOVERN

Q. And where it starts heading up to 4 percent, that appears to be quite a cluster of infections right around those -- that several-month time period?

A. Yes.

Q. Do you recall that that several-month time period actually corresponded with the time that the hospital had switched to using rivaroxaban instead of the tinzaparin as the anti-thromboembolism prophylaxis?

A. I don't recall.

Q. Do you remember that there was a time the hospital switched from tinzaparin to rivaroxaban?

A. I am aware that there was a transition, yes.

Q. And do you remember that after some period of time, the hospital switched back to tinzaparin?

A. That sounds familiar to me. I wasn't aware that they had switched back wholesale. I knew that there were changes in thromboprophylactic medications.

Q. When did you leave Wansbeck?

A. It would have been about February 2010. Yes.

Q. Okay, so that would have been --

A. No, it might have been earlier. Around February 2010.

Q. And you don't recall, around the time that you were leaving, that there were -- hearing any conversations about

Page 120

DR. PAUL MCGOVERN

"Wow, we've got a real spike in issues with this, with the rivaroxaban?"

A. I have a recollection that some patients who'd had -- well, various orthopedic operations, had more strike-through on their dressings, that is to say more ooze from post-operative wounds, but I don't remember any discussions about infection rates around that time.

Q. Why was figure 7, as it appears on 2218, changed to the flatline averages that appear in the subsequent ones, and the one that was ultimately published?

MR. SACCHET: Object to form.

A. I don't know.

BY MR. C. GORDON:

Q. Did you have any input into that decision?

A. No.

Q. Do you recall ever seeing the version that we see on page 2218?

A. I don't recall seeing it at the time. I've flicked through all of these documents but I don't remember a discussion around changing this, or the process of it being changed.

Q. And you don't recall anyone expressing the view that "Hey, the way it looks on" -- as we see it on 2218 -- "it looks like there's some problem going on there in that

Page 121

DR. PAUL MCGOVERN

last few months of the Bair Hugger-only period?"

MR. SACCHET: Object to form.

MR. C. GORDON: I actually need another exhibit sticker.

THE COURT REPORTER: Do you want me to mark it first?

MR. C. GORDON: Sure. Your handwriting is better.

A. I don't remember any discussions of that nature.

(Exhibit 11 marked for identification)

Q. Dr. McGovern, I'm going to show you what has been marked as exhibit 11. I'll give you a moment to look at that and see if you've ever seen it before.

A. It's possible that I've seen this, but I don't recall it.

Q. Do you know who Julie Jillson is, or Gillson?

A. I do not. I don't know who they are.

Q. So you don't know who Gail Lowdon is either?

A. No, I don't know who Gail Lowdon is.

Q. Okay. On the first page, I'm going to direct your attention to the very last paragraph where it says:

"During the last two quarters of 2008/2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in THR/TKR and Repair Neck of Femur between 3.5%-5% and

31 (Pages 118 to 121)

Page 122

1 DR. PAUL MCGOVERN
2 was regularly receiving letters from the HPA informing
3 the Trust of its high outlier status for SSI."

4 Did I read that correctly?

5 A. Yes.

6 Q. Does that trigger any recollections from when you
7 started there, as to concerns that were -- that they -- that
8 the Trust was in an outlier status in terms of its SSI
9 rates?

10 A. It does. There were discussions and concerns about
11 the infection rate, as I remember, in the Trust, and as a
12 result, there was certainly an effort to implement good
13 theater discipline to try to minimize the infection rate.

14 Q. Were you aware of any specific interventions that
15 took place during the time that you were there?

16 A. Yes. I don't remember if they started before or
17 after I arrived, but for example, in this healthcare trust,
18 there was a red line beyond -- in the operating department
19 beyond which you had to change into different scrubs. So
20 frequently it's -- in some hospital trusts, it's standard
21 to -- for doctors, or for healthcare professionals, to wear
22 scrubs around the hospital and enter the operating
23 department in the same scrubs. But on crossing the red line
24 in Northumbria, one had to completely change, even if going
25 in for 20 seconds. Even if you were going in to speak to

Page 123

1 DR. PAUL MCGOVERN
2 someone. So there was a barrier.

3 All footwear was not individualized, it was --
4 there were racks of new footwear provided in the special
5 footwear-washing station, so footwear was washed every
6 day. Particular attention was paid to good theater
7 discipline, which is standard practice, but there was
8 definitely a -- efforts were definitely made to maintain
9 the very highest standards of care. And I don't
10 remember any other specific interventions, but I'm sure
11 there were more.

12 Q. Do you remember a time when the Trust implemented
13 screening for methicillin susceptible staphylococcus?

14 A. It rings a bell. I don't remember at what time
15 they did that. I don't remember a particular crossover
16 point when screening for MRSA and MSSA was different, so
17 I don't have a specific recollection of that happening,
18 although it seems familiar to me to -- that MSSIs were --
19 methicillin-sensitive staphylococcus aureus was screened
20 for. I don't remember the specifics around that, though.

21 Q. Do you remember a time when the laminar flow system
22 in one of the operating theaters was not functioning
23 properly and had to be repaired?

24 A. I do not remember that.

25 Q. If you turn to the second page of exhibit 11, in

Page 124

1 DR. PAUL MCGOVERN
2 the middle there it talks about -- the headline is "The SSI
3 bundle."

4 A. Yes.

5 Q. And it talks about Patient Safety First published
6 in SSI bundle in 2009.

7 A. Yes.

8 Q. Now if I could have another exhibit sticker.
9 (Exhibit 12 marked for identification)

10 I'm showing you what has been marked as
11 McGovern exhibit 12. It's like a 32-page document
12 called "The 'How to' Guide for reducing Harm in
13 Perioperative Care, Patient Safety First."

14 I first ask if you recognize this document.

15 A. It's quite likely that I've come across it before,
16 but I don't specifically recall it.

17 Q. Going back to exhibit 11, where it says "The SSI
18 group decided to utilise this tool to develop a strategy to
19 reduce the Trust's SSI rate."

20 Do you recall there being a period of time -- and
21 you were there in 2009, right?

22 A. I was there from August 2009.

23 Q. Okay. So do you recall whether, while you were
24 there, something similar to exhibit 12 was somehow
25 distributed or utilized by the surgical staff?

Page 125

1 DR. PAUL MCGOVERN

2 A. In terms of --

3 MR. SACCHET: Object to form.

4 A. -- in terms of documentation, not that I recall.
5 As I said, there was an acknowledgment in the department
6 that the infection rate was higher than what would be --
7 well, preferred, and there were efforts to reduce it, though
8 I don't recall documentation to that effect, but there was
9 certainly a cultural drive within the orthopedic department
10 and within the surgical department in general, to minimize
11 infection rates.

12 BY MR. C. GORDON:

13 Q. Do you recall a period of time when the type of
14 wound dressings were switched?

15 A. I do recall that, yes, there was a different type
16 of wound dressing used at some point. Yes, I do recall
17 different wound dressings being used.

18 Q. Do you recall a wound dressing referred as to the
19 Jubilee dressing?

20 A. I'd forgotten the name, but I remember vaguely the
21 technique.

22 Q. What was your understanding of the reason for the
23 change in wound dressing?

24 A. I think the dressing was -- I don't remember what
25 the intention of the dressing was, apart from to make sure

EXHIBIT DX11

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

23/11/2016

Gmail - Barely made it with the new sample numbers



Paul McGovern <pdmcgovern@gmail.com>

Barely made it with the new sample numbers

2 messages

Mark Albrecht <malbrecht@augbiomed.com>

31 January 2011 at 15:44

To: Mike Reed Cons Wansbeck <mike.reed@nhs.net>, Paul McGovern <pdmcgovern@gmail.com>
 Cc: Scott Augustine <saugustine@augbiomed.com>, Christopher Nachtsheim <nacht001@umn.edu>

Gents,

Attached is a updated chart of the infection data. The difference is significant, based upon the results of logistic regression. Some highlights:

-Infection rates were: 3.10% for forced air (n=1065), 3.75% for the transition period (n=160), and 1.08% for conductive fabric warming (n=372)

-Infection rates for Forced air warming vs Conductive Fabric Warming were significantly different (p=0.0429)

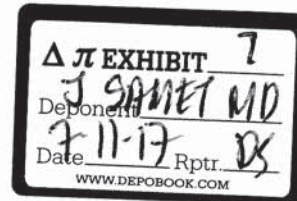
-Infection rates for Forced air warming vs Transition period were not significantly different (p=0.662)

-Infection rates for Conductive Fabric Warming vs Transition were marginally significant (p=0.0504)

Ok, we made it here to a significant difference, so I'll update the manuscript to reflect the new infection numbers. I'll also dig into the difference between hip and knee in the data and get back to you on that.

First results look good though...

-Mark



Updated_fig_1.tiff
2108K

Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH)
 <mike.reed@nhs.net>

31 January 2011 at 15:56

To: Mark Albrecht <malbrecht@augbiomed.com>, Paul McGovern <pdmcgovern@gmail.com>
 Cc: Scott Augustine <saugustine@augbiomed.com>, Christopher Nachtsheim <nacht001@umn.edu>

Excellent - delighted it still comes in as significant. Even if it didn't I think it would just need more time.
 Thank you very much for doing..
 Mike

From: Mark Albrecht [malbrecht@augbiomed.com]**Sent:** 31 January 2011 15:44**To:** Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH); 'Paul McGovern'**Cc:** 'Scott Augustine'; 'Christopher Nachtsheim'**Subject:** Barely made it with the new sample numbers

[Quoted text hidden]

<https://mail.google.com/mail/u/0/?ui=2&ik=eab3bab86&view=pt&q=augustine&as=true&search=query&th=12ddcbfeb58897e1&siml=12ddcbfeb58897e1&...> 1/2

23/11/2016

Gmail - Barely made it with the new sample numbers

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EXHIBIT DX12

TO DECLARATION OF COREY L. GORDON
IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE
TESTIMONY OF THEODORE HOLFORD AND
JONATHAN BORAK

**FAEGRE BAKER
DANIELS**

**IN THE HIGH COURT OF
JUSTICE**

CLAIM NO: CR 2016-520

QUEENS BENCH DIVISION

**IN THE MATTER OF
THE EVIDENCE (PROCEEDINGS IN OTHER JURISDICTIONS) ACT 1975**

AND

IN THE MATTER OF CPR PART 34

AND

**IN THE MATTER OF A CIVIL MATTER NOW PROCEEDINGS BEFORE THE UNITED STATES DISTRICT
COURT FOR THE DISTRICT OF MINNESOTA ENTITLED AS FOLLOWS:**

IN RE: BAIR HUGGER FORCED AIR WARMING

MDL NO. 15-2666(JNE/FLN)

PRODUCTS LIABILITY LITIGATION

Plaintiffs

-v-

3M COMPANY AND ARIZANT HEALTHCARE INC.

Defendants

**DOCUMENTS PROVIDED
BY DR PAUL MCGOVERN
VOLUME 6**

PAGES 2529 - 2989



Document Name: Response to Reviewer Comments (1).docx

Log No: 27124

Title: Forced Air Warming and Ultra-Clean Ventilation Do Not Mix: An Investigation of Theatre Ventilation, Patient Warming and Joint Replacement Infection in Orthopaedics

Editor's Comments: None

Reviewer Comments:

Reader 1

Comments: Having been associated with Sir John Charnley during the development of the clean air concept, as long ago as 1959, I find it truly amazing that the basic principle that exclusion of bacteria-bearing particles from the wound is useful should still be scrutinised after such a long time. The genius of Charnley, after the greenhouse era, continued with respect to the eddying effect of any structure impeding the downward laminar flow by, in the prototype enclosure, the lights were kept outside the glass walls. Again, if the bubbles are demonstrating pollution from the floor, there must be something wrong with the body exhaust suits shown in the illustrations.

• The authors refer to the several publications that tend to disparage, or even deny, the efficacy of the clean air facility. None of the recent such publications are conclusive because not all sources of potential contamination are taken into consideration: the large New Zealand Registry findings are notable in this respect. Comment by the authors regarding the assessment of contamination by bacterial culture of wash-out samples or simple use of the slit sampler should be added, these being basic endpoints of air pollution.

We agree with your sentiments regarding the efficacy of laminar flow ventilation for the reduction of both surgical site contamination exposure and infection rates: the only randomized study ever conducted (in the 1970's) showed benefits for both of these outcomes and we do think such systems are important components of an infection reduction strategy in modern Orthopaedic surgery. Sadly, though, not all clinicians agree with our viewpoint and recent observational research, albeit flawed in some respects, has been used to disparage laminar flow and give "teeth" to their arguments. Thus, as you suggest the addition of a comment addressing the flaws inherent in these national studies is fully warranted. We address this point in the manuscript with the following modification to 6th paragraph of the discussion as follows:

"National studies on the benefits of laminar flow ultra-clean ventilation may provide a better indication as to the impact of forced air warming on contaminant mobilization for they take into account the full range of surgical draping, procedural practices, and theatre dress. Over the past 10 years, these studies have shown either an upwards trend towards³² or significantly higher^{33,34} infection rates in laminar flow. Yet, the results of these studies are not fully conclusive for they are limited by their clinical design, which omits basic air pollution endpoint measurements (wound wash-out or slit sampling). Moreover, the mobilization of non-sterile air due to forced air warming use may be the explanatory factor, since historical studies^{1,3} on laminar flow ventilation conducted before the introduction of forced air warming showed clear infection reduction benefits. Additionally, the widespread acceptance that forced air warming reduces infection rates has only been demonstrated in colorectal surgery.³⁵"

• Bacteria sampling conducted by Tumia et al reveals the inadequacy of data on which conclusions can be based, but the matter of forced air contamination was known as long as 9 years ago. Microbiologists visit the operating theatre remarkably infrequently and yet contamination studies are commonly published by them outside the orthopaedic literature. I do not recall the importance of the surgeon being recommended to be aware of what his anaesthetist colleague may or may not be doing in this matter having appeared in our Journal. For these reasons with some adjustment, the Paper is useful.
We agree.

• A picture showing the actual bubbles would be informative in addition to the blurred distance view labelled: convection.

As suggested we have added a photo to Figure 3 showing the bubbles exiting the diffuser.

The hip operating surgeon has a full body exhaust suit whereas the spine operator has a mask and open neck garb that we found very leaky at the hip wound area as measured by slit-sampling.

We wanted our theatre dress during the study to reflect current clinical practice. However, you might be right in that we should consider updating our operating theatre dress protocols for spinal procedures, particularly if such practices are exposing the surgical site to added airborne contamination. In the manuscript, we made a small comment regarding theatre dress in the methods section:

“ Experimental Setup: Lumbar Spinal Procedure

The same mannequin was laid in the prone position on the operating table and four drapes were arranged in a “square” configuration (MoInlycke Health Care) with the anaesthesia/surgery screen at full-height (Fig 2). A single surgeon stood motionless next to the surgical site for all experiments. As is common in contemporary practice, a standard theatre gown was worn by the surgeon, with face mask. The lower-body warming treatment was introduced under the drape and was either: 1) a lower-body forced air blanket (Bair Hugger Model 525, Arizant Healthcare); or 2) a lower-body conductive fabric blanket (Hot Dog Model B103, Augustine Temperature Management). The blankets were powered by the same controllers as listed above and set to 43°C. “Bubbles” were introduced at floor level between the surgeon’s body and the operating theatre table in the region where the patient warming excess heat was being released.”

Minor changes.

Reader 2

This is a paper on a matter of critical importance to arthroplasty surgeons. It is also topical due to the recent publication of NICE guidelines about the prevention of hypothermia in the surgical patient.

It is therefore particularly pleasing to find this paper which deals with the issue of forced-air warming in the sterile field of such surgery in a clear, methodical and productive fashion. The paper is well written. There are data from their experiments with 'Mock' surgery and airflow investigation and those demonstrate definite differences in air flow between the different methods of draping, the different surgical set-ups and the different types of warming apparatus. I found this easy to read, informative and likely to change peoples' practice.

The second part of the paper is a study of the infection in the cases done in their unit over a period of years before, during and after the transition from the forced-air warming apparatus to the conductive material heating apparatus. This demonstrates that there were actual changes in infection rates which would fit well with the experimental data and therefore support the contention that there is a serious issue to be addressed with some of the warming devices. I do have a few minor queries:

1) Given the variation in temperature and air flow, how was it determined that the bubbles were and remained 'neutrally buoyant'? Does it matter if they did not?

The bubble generator (although it sounds like a toy!) is a complex piece of scientific equipment. It actually has a centrifugal classifier that separates any bubbles from the stream that are not truly "neutrally buoyant." In action, the centrifugal classifier only allows a very small proportion of bubbles - those having a perfect size, glycerin soap wall thickness, and helium/air ratio - to pass through the system. Those heavier or lighter than "buoyant" are discarded. That is why we can say that the bubbles are "perfectly sized" and "neutrally buoyant".

As a side note, this piece of equipment (sage action bubble generator #5) is commonly used by NASA and other high tech engineering firms to study airflows. There are actually quite a few published papers out there, but only a couple in the medical literature.

In the interest of brevity, we suggest making no changes to the manuscript and leave it for the reader to investigate further, should they desire. We are very happy to take the reviewers advice on this.

2) Was the draping for arthroplasty done with the end of the single main drape of the surgical site raised up at the anaesthetic end of the table, or was the anaesthetic exclusion drape a separate drape altogether? If the former, do they think this makes a difference? If the latter do they think

it would make a difference how the two drapes were sealed at their junction and what shape the drape is?

Draping was done with the “former” configuration, where the head-end of the main drape was elevated. Given that this configuration was in accordance with standard hospital draping procedures, we chose to use this setup for the study. Additionally, all three drapes had adhesive edges that were secured in the vicinity of the surgical site to create one “uniform” drape.

Would it matter if a separate drape were used to form the anesthetic exclusion drape?... Probably not since the forced air blanket could not be fully separated from the anaesthetic drape end (keep in mind we are using a torso blanket for the arthroplasty that even vents exhaust on the patient’s neck and head). The reality of the situation is that the heated forced air exhaust simply builds up under the drapes, regardless of the shape. A constant flow of 40 ft³ of heated air is being pumped under the drapes every minute. This heated air pools under the “drape tent” until it finds an escape point, which is always the segment of the drape that is elevated near the forced air blanket. The anesthetic screen is always much higher than the adjoining drape segments, so that is where the heated exhaust naturally exits.

Of course, the shape of the drape matters critically in terms of the edge that is elevated. That is why we added “anesthetic drape height” as a 3-level factor to the study. We wanted to see what effect drape shape did, indeed, have on convection current formation.

To address these comments we modified the explanation of the drape setup in the manuscript Methods section as follows:

“Experimental Setup: Hip Replacement

A mannequin was laid in the lateral position on an operating table and draped with a 3-piece orthopaedic kit (Molnlycke Health Care, Manchester, UK) in accordance with standard protocols (Fig 1). Drapes had adhesive edges and all adhesive seams were sealed during draping. A surgeon, dressed in occlusive clothing with head gear (T4, Stryker, Kalamazoo, MI), stood motionless in front of the surgical site. An anaesthetist at the head end of the operating table. The head end of the drape was used to create an anaesthesia screen in one of three positions, either: 1) clipped to the ceiling to create a barrier between the surgical site and anaesthesia area (full-drape); 2) clipped to IV poles and raised 0.75 metres above the operating table (half-drape); or 3) laid-down over the mannequin’s head (laid-down). The upper-body warming treatment was introduced under the drape and was either: 1) a torso forced air blanket (Bair Hugger Model 540, Arizant Healthcare, Eden Prairie, MN); or 2) a torso conductive fabric blanket (Hot Dog Model B110, Augustine Temperature Management, Eden Prairie, MN). The blankets were powered by standard controllers set to 43°C (conductive fabric - Model WC02, Augustine Temperature Management; forced air - Model 750, Arizant Healthcare). “Bubbles” were introduced at the head/neck of the mannequin to track under-drape resident air movements in the region where the excess patient warming heat was being released.”

3) What proportion of infections, either deep OR superficial, are likely to be missed by a cut-off at 60 days post-op?

For deep infection, we chose the post-op cutoff to be a fixed 60 days because that captured 100% of infections meaning that for the n=1437 patients, those whom developed an infection did so within the first 60 days. Just for your information, if we had chosen a 30 day cutoff we would have missed 10.9% of deep joint infections.

We chose not to assess superficial infections because it is a softer endpoint and perhaps not as robust. In addition it may be less attributable to in theatre contamination. We felt that the inclusion of superficial infection data would dilute the results and distract the reader from the core issue of study: airborne contamination exposure and its relationship to implant infection (i.e. deep infection).

4) Is there any reason to suppose (from the presumably PARTIAL information that they DO have) to believe that the demographics for the factors they identify under 'joint infection risks' would actually have been different in the cohorts before, during and after the transition from one heating device to the other?

We have no reason to believe or information suggesting that the two patient groups are different in any significant or clinically relevant manner, aside from changes to antibiotic regimes (see #7). The patients were consecutive and unselected.

Changes were made to the Results section in the manuscript as follows:

“Joint Infection Risks:

Patient demographics over n=1437 cases for the surgical site infection risk factors of age, surgery type, diabetes, and length of preoperative stay were not significantly different between the patient warming groups (Table 1); record keeping was incomplete for the additional risk factors of blood transfusion, obesity, incontinence, and fitness for surgery, which have been identified elsewhere as important predictors for deep infection.^{4,17} In regards to these unobserved factors, the authors have no reason to believe that significant differences existed between cohorts, thus, infection risks should be similar for both groups. “

5) It does seem very odd that the infection risk for THR is 4 times higher than for TKR. Is this actually what they mean? This would be roughly the reverse of that usually expected at least for

deep infections. If true is there any explanation they can offer? Were the THR cases done in the lateral position? Did the surgeons wear Hoods and/or Body exhaust suits?

The odds ratio for developing deep infection during hip replacement versus total knee was indeed 4.1, suggesting a significant elevation in infection rates for the hip arthroplasty. We are presently puzzled as to why this is the case since these results challenge standard assumptions regarding infection risks for each surgery type. As a note:

- *Hip replacement was performed in the lateral position*
- *The same space suits were worn during all hip and knee procedures*

As such, the reason for this infection rate difference is presently unknown. It may, potentially, be due to airflow differences in the vicinity of the wound, but that is all we can suggest at this time...

To address this, the following changes were made to the Discussion section of the manuscript (see the changes in point #6 where both #5 and #6 are jointly addressed)

See Below

6) Were there any differences between the THR and TKR groups in the change in infection rate seen after the move to the new body warming device?

Unfortunately, we simply don't have enough data to answer such a detailed question; for the logistic regression model, we only had 3 deep joint infections in the conductive fabric warming group (1 knee and 2 hip infections). Differences in infection risks between cohorts cannot reliably be estimated. However, we can do a quick check of infection odds-ratios for both patient warming subgroups to see if there is an apparent or obvious change. Such calculations were performed and no meaningful differences were found (odds-ratios of 3.5 versus 4.1 for conductive fabric and forced air, respectively). We added this information to the manuscript.

To address this point and question #5 we added several changes to the Manuscript in the Results, Discussion, and Table 2 as follows:

*“The risks of deep joint infection (**Table 2**) were significantly greater for: 1) patients undergoing hip versus knee replacement (odds-ratio 4.1, $p < 0.001$); and 2) patients treated with forced air versus conductive fabric warming (odds-ratio 3.8, $p = 0.028$). The factors of age, diabetes, and pre-operative length of stay had no significant impact on infection risks. Further, the hip versus knee infection odds-ratios were similar for the patient warming subgroups of forced air and conductive fabric having values of 4.1 and 3.5, respectively.”*

“The clinical concern regarding the formation of such convection currents is two-fold. First, these currents oppose the natural clean-airflow patterns that are intended to sweep contaminants down and

away from the surgical site.²⁰ Thus, contaminants released in the vicinity of the surgical site are less likely to be cleared. Second, the upward mobilisation of floor-level and under-drape air could potentially compromise the sterility of the surgical site, since resident air from these locations is typically laden with pathogens shed from the surgical staff.²¹ Either mechanism offers a plausible explanation as to the significant association between patient warming device and joint infection risks in this study. Further, the types of organisms isolated from septic joints were predominately skin flora and, therefore, likely to have been transmitted and deposited from the air.²² It was, however, somewhat unusual that the odds of hip arthroplasty infection were 4.1 times greater than the odds for knee; typically, infection risks are greater for knee arthroplasty.²³ A check of surgical practices revealed no differences in theatre dress nor significant differences in draping techniques between the procedures. Further, the infection odds ratio was consistent for both the forced air and conductive fabric sub-groups (3.5 and 4.1, respectively), which suggests that there were no apparent changes in risk factors aside from patient warming device. “

	No. (%) Developing Infection	No. (%) Not Developing Infection	Odds Ratio (95% Confidence Interval)	P value
Age				0.818 ^a
Youngest 1/3 (≤64)	13 (2.7)	472 (97.3)	1.0	
Middle 1/3 (>64 and ≤72)	12 (2.5)	459 (97.5)	0.9 (0.4, 2.1)	
Oldest 1/3 (≥73)	10 (2.1)	471 (97.9)	0.8 (0.3, 1.8)	
Type of Surgery				<0.001 ^a
Knee	10 (1.1)	869 (98.9)	1.0	
Hip	25 (4.5)	533 (95.5)	4.1 (1.9, 8.6)	
Diabetes				0.110 ^a
None	34 (2.7)	1219 (97.3)	1.0	
Type I or II%	1 (0.5)	183 (99.5)	0.2 (0.0, 1.4)	
Preoperative Stay				0.327 ^a
0 Days	34 (2.5)	1310 (97.5)	1.0	
1 or More Days	1 (1.1)	92 (98.9)	0.4 (0.1, 3.1)	
Patient Warming Device				0.028 ^a
Conductive Fabric	3 (0.8)	368 (99.2)	1.0	
Knee	<u>1</u>	<u>235</u>		
Hip	<u>2</u>	<u>133</u>		
Forced Air	32 (3.0)	1034 (97.0)	3.8 (1.2, 12.5)	
Knee	<u>9</u>	<u>634</u>		
Hip	<u>23</u>	<u>400</u>		

7) I think it would be a good idea if they could include details of the changes to their VTE prophylaxis regime and their antibiotic regime that were altered during the course of the study. How were they altered and exactly when during the process

These details were added to the results section of the manuscript as follows:

"The antibiotic regime over the course of the study was as follows: July 2008 to February 2009, single dose of Gentamicin 4.5mg/kg at induction; March 2009 to end of study, Teicoplanin 400 mg and gentamicin 3mg/kg. Gentamicin loaded cement (0.5g per 40g mix) was used for both groups. Similarly, the thromboprophylaxis regime was as follows: July 2008 to August 2010, Tinzaparin from day one post-op; August 2010 to February 2010, Rivaroxaban from day on post-op; February 2010 to end of study, Tinzaparin from day one post-op."